Supporting Statement for Paperwork Reduction Act Submissions

A. Background

This information collection package is a request for new information collection requirements as they relate to 42 CFR 424.22; "Requirements for Home Health Services". With this submission, we are revising an existing PRA package for home health agencies to also request new information collection requirements.
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 (INSERT DATE) changes the certification requirements for Home Health Agencies. This rule implements a provision of the Patient Protection and Affordable Care Act (PPACA) which was signed by President Obama on March 23, 2010. To implement this provision of PPACA, CMS proposes to revise §424.22 such that for initial certifications, prior to a physician signing and dating that certification and thus certifying a patient's eligibility for the Medicare home health benefit, the physician responsible for certifying the patient for home health services must document that a face-to-face patient encounter (including through the use of teleheath if appropriate) has occurred no more than 30 days prior to the home health start- of- care date by himself or herself, or within 2 weeks of start of care, by an authorized non-physician practitioner (as specified in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) working in collaboration with or under the supervision of the certifying physician as described above._

Below we also describe proposed clarifications to therapy coverage regulations at §409.44. These coverage clarifications include documentation expectations associated with the provision of therapy in the home health setting. These sections are included here for information purposes only. The documentation expectations described in our proposed coverage regulatory changes are long standing requirements mandated by the existing hoem health condition of participation regulations, and some are also currently mandated in existing manual guidance. As such, no additional burden is associated with these clarifications.

B. 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 Patient Protection and Affordable Care Act (PPACA) of 2010 (Pub. L., 111-148) was enacted. Section 6407(a) (amended by section 10605) of the PPACA 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 specified non-physician practitioner has had a face-to-face encounter (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act)", with the patient.

The PPACA 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.

Basis for Revisions 42 CFR 424.22(a)(1)(v) associated with CY 2011 Proposed Rule

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require a plan of care for furnishing home health services be established and periodically reviewed by a physician in order for Medicare payments for those services to be made. The physician is responsible for certifying that the individual is confined to his or her home and needs skilled nursing care on an intermittent basis or physical or speech therapy. The plan for furnishing such services has to be established, and updated when appropriate, by the beneficiary's physician.

As described in the background section, the Patient Protection and Affordable Care Act (PPACA) of 2010 (Pub. L., 111-148) requires that, prior to certifying a patient as eligible for the home health benefit , the physician must document that the physician himself or herself or specified non-physician practitioner has had a face-to-face encounter (including through the use of telehealth, subject to the requirements in section 1834(m) of the Act) with the patient.

PPACA describes non-physician practitioners who may perform this face-to-face patient encounter as a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1861(aa)(5)of the Act,) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg)of the Act, as authorized by State law), or a physician assistant (as defined in section 1861(aa)(5)of the Act),in accordance with State law and under the supervision of the physician. The PPACA provision does not amend the statutory requirement that a physician must certify a patient's eligibility for Medicare's home health benefit. Rather the provision allows for specific non-physician practitioners to perform the face-to-face encounter with the patient in lieu of the certifying physician, and inform the physician making the initial certification for eligibility for the Medicare home health benefit. The certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted non-physician practitioners perform the face-to-face encounter. PPACA gives the Secretary the discretion to set a reasonable timeframe for this encounter.

We believe that the face-to-face encounter statutory provision was enacted to strengthen physician accountability in certifying that home health patients meet home health eligibility requirements. We also believe that in order to achieve this goal, the encounter must occur close enough to the home health start of care to ensure that the clinical conditions exhibited by the patient during the encounter are related to the primary reason for the patient's need for home health care. As such, we believe that encounters would need to occur closer to the start of home health care than the six month period prior to certification recommended, but not required by PPACA for Part B services. Therefore we propose revising §424.22 such that for initial certifications, prior to a physician signing that certification and thus certifying a patient's eligibility for the Medicare home health benefit, the physician responsible for certifying the patient for home health services must document that a face-to-face patient encounter (including through the use of teleheath if appropriate) has occurred no more than 30 days prior to the home health start-of-care date or within 2 weeks of the start of care by himself or herself, or by an authorized non-physician practitioner (as specified in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) working in collaboration with or under the supervision of the certifying physician as described above.

We believe that in many cases, a face-to-face encounter with a patient within the 30 days prior to the home health episode start of care will provide the certifying physician a current clinical presentation of the patient's condition such that the physician can accurately certify home health eligibility, and in conjunction with the home health agency, can establish an effective care plan. We also believe that, a face-to-face encounter which occurs within 30 days prior to the home health start of care would be generally relevant to the reason for the patient's need for home health services, and therefore such a face-to-face would be sufficient to meet the goals of this statutory requirement. However, if a face- to-face encounter occurs within 30 days of the start of the home health episode, but the clinical condition of the patient changes significantly between the time of the face-to-face encounter and the home health episode start of care such that the primary reason the patient requires home health care is unrelated to the patient's condition at the time of the face-to-face encounter, this encounter

would not satisfy the requirement. Rather, in this case, we propose revising §424.22 such that the certifying physician, or authorized non-physician practitioner, must have another face-to-face encounter (which may include the use of telehealth, subject to the requirements in section 1834(m) of the Act and subject to the list of Medicare telehealth services established in the most recent year's physician fee schedule regulations), with the patient within two weeks after the start of the home health episode. The certifying physician must document the face-to-face encounter, along with the clinical findings of that encounter as part of the signed certification. Because the patient's clinical condition significantly changed, we believe that a more contemporaneous visit is needed to ensure the certifying physician can accurately certify the patient's eligibility for services, and effectively plan the patient's care.

Similarly, we propose to revise §424.22to reflect that if a home health patient has not seen the certifying physician or one of the specified non-physician practitioners as described above, in the 30 days prior to the home health episode start of care, the certifying physician or non-physician practitioner, would be required to have a face-to-face encounter (including the use of telehealth, subject to the requirements in section 1834(m) of the Act and subject to the list of Medicare telehealth services established in the most recent year's physician fee schedule regulations) with the patient within two weeks after the start of the home health episode to comply with the requirements for payment under the Medicare Program.

We also propose to revise §424.22) such that the certifying physician's documentation of the face-to-face encounter would clearly state that either the certifying physician himself or herself, or the applicable non-physician practitioner has had a face-to-face encounter with the patient and would include the date of that encounter. The documentation would also describe why the clinical findings of that encounter supported the patient's eligibility for the Medicare home health benefit. Specifically, the physician would document how the clinical findings of the encounter supported findings that the patient was homebound and in need of intermittent skilled nursing and/or therapy services, as defined in 409.42(a) and 409.42(c) respectively.

Again, the certifying physician's documentation of the face-to-face patient encounter would be either a separate and distinct area on the certification or a separate and distinct addendum to the certification that was easily identifiable and clearly titled.

If an allowed non-physician practitioner was conducting the face-to-face visit, that practitioner would have to document the clinical findings of the face-to-face patient encounter and communicate those findings to the certifying physician, so that the certifying physician could document the face-to-face encounter accordingly, as part of the signed certification. Section §409.41 of the CFR states that in order for home health services to qualify for payment under the Medicare program the physician certification requirements for home health services must be met in compliance with Section 424.22. Therefore, if the patient's certifying physician did not document that a face- to- face encounter occurred no more than 30 days prior to the home health start of care date or two weeks after the start of care date, the services would not qualify for payment under the Medicare program.

Basis for Revisions to §409.42(c)(1), 409.44(b), and §424.22 Associated with CY 2010 Final Rule

In recent years, MedPAC, Medicare Contractors and the HHS Office of the Inspector General (OIG), and Medicaid State agencies suggested the need for CMS to clarify the Medicare home health coverage criteria regarding the skilled services specified at §409.42. In their March 2004 report (http://www.medpac.gov/documents/Mar04_Entire_reportv3.pdf), MedPAC reported that the Medicare eligibility criteria for the home health benefits leaves a great deal open to interpretation, describing a particular concern with the lack of clarity regarding the Medicare home health skilled nursing services requirement. In their Memorandum Report dated February 5, 2009 titled "Medicaid and Medicare Home Health Payments for Skilled Nursing and Home Health Aide Services" (http://oig.hhs.gov/oei/reports/oei-07-06-00641.pdf), the OIG also stated that Medicare coverage policy regarding skilled nursing services lacked clarity. The OIG indicated that our payment methodology might be prone to error. HHAs were unclear about which skilled nursing services were covered by Medicare's home health benefit. Further, Medicaid State agencies have also communicated to CMS their concerns that HHAs find it difficult to accurately determine when services provided to dually Medicare and Medicaid eligible individuals ("dual eligibles") meet the Medicare coverage criteria, especially the requirements for needing skilled nursing care on an intermittent basis. State Medicaid agencies have communicated to CMS that this ambiguity is resulting in some HHAs routinely submitting all claims for dual-eligible persons with chronic care needs to their State Medicaid agencies for payment. State Medicaid agencies and CMS are concerned about this practice, referencing the requirement under the Social Security Act that Medicaid must be the payer of last resort.

In 2006, CMS and certain Medicaid states embarked on an educational initiative to improve the ability of HHAs, States, and CMS contractors to make appropriate coverage decisions, resulting in an improved ability by HHAs to identify the appropriate payer for services provided, ultimately improving HHA billing accuracy.

As part of its provider education program, CMS focused on clarifying §409.42 "Beneficiary qualifications for coverage of services". During the course of the training, it became apparent that confusion existed among certain states and HHAs regarding under what circumstances the overall management and evaluation of a care plan would constitute a skilled service. HHAs asked what underlying conditions, complications, or circumstances would require a patient otherwise receiving unskilled services to need care plan management and evaluation by a registered nurse, thus rendering such care skilled. CMS therefore ensured that the training provided a particular focus on the requirement that a beneficiary be in need of skilled services. CMS provided comprehensive guidance to clarify that in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. Another area of confusion that surfaced during the training was when the need for patient education services

constitutes skilled services in the home health setting. HHAs questioned which specific sorts of educational services would render the education a skilled service in the home health setting.

To address the concerns identified by OIG, MedPAC, State Medicaid agencies and the clarity concerns home health agencies communicated to CMS during the 2006 training, we propose to revise §409.42(c)(1) to further clarify that in order for services to be considered skilled in the home health setting, certain limitations (discussed below) would apply. We believe these revisions would assist HHAs in their determination of home health eligibility and will enable HHAs to more accurately bill for their dual eligible population.

Basis for revisions to §409.42(c)(1) Associated with CY 2010 Final Rule

To clarify what constitutes skilled services in the home health setting, in final rulemaking we have made the following revision to §409.42. We are adding a qualifying instruction to §409.42(c)(1) to explain that intermittent skilled nursing services meeting the criteria for skilled services and the need for skilled services found in §409.32 (with examples in §409.33 (a) and (b)) are subject to certain limitations in the home health setting. We propose to describe the limitations in two new paragraphs, §409.42(c)(1)(i) and §409.42(c)(1)(ii).

Basis for new paragraph §409.42(c)(1)(i) Associated with CY 2010 Final Rule

Our policy at §409.33(a)(1) describes that the development, management, and evaluation of a patient's care plan based on physician's orders constitute skilled services when, because of the patient's physical or medical condition, oversight by technical or professional personnel is needed to promote recovery and ensure medical safety. The examples described in §409.33(a)(1)(ii) further describe that when the patient's overall condition supports a finding that recovery and safety can be ensured only if the total care is planned, managed, and evaluated by technical or professional personnel, it is appropriate to infer that skilled services are being provided.

As such, we have also revised §409.42(c)(1)(i) to say that in the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose.

Further, in §409.42(c)(1)(i) we have clarified that to be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the nonskilled services being provided to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service.

Additionally, we have further clarified in §409.42(c)(1)(i) that in some cases, the condition of the patient may require that a service that would normally be considered unskilled be classified as a skilled nursing service given a patient's unique circumstances. This would occur when the patient's underlying condition or complication required that only a registered nurse could ensure that essential non-skilled care was achieving its purpose. The registered nurse would ensure that services were safely and effectively performed. However, any individual service would not be deemed a skilled nursing service merely because it was performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by the average non-medical person without the direct supervision of a nurse, the service cannot be regarded as a skilled service although a nurse actually provided the service.

Basis for new paragraph §409.42(c)(1)(ii) Associated with CY 2010 Final Rule

Additionally, we have added a new §409.42(c)(1)(ii), which clarifies when patient education services as described in §409.33(a)(3) constituted skilled services in the home health setting. Current §409.32(a)(3) states that patient education services are skilled services if the use of technical or professional personnel is necessary to teach patient self-maintenance. However, to address the concerns and lack of clarity surrounding when educations services are skilled services as described above, we have added a new paragraph, §409.42(c)(1)(ii). In the home health setting, skilled education services are to be deemed no longer needed when it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver cannot or will not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

Basis for change to §409.44(b) Associated with CY 2010 Final Rule

We have revised the introductory material at §409.44(b)(1), to refer to the newly proposed limitations of skilled services in the home health benefit at §409.42(c)(1)(i) and 409.42(c)(1)(ii). The clauses under the revised paragraphs (i) through (iv) would remain unchanged.

Basis for revisions to §409.44(c)(2)(i) Associated with CY 2011 Proposed Rule

We propose revising §409.44(c)(2)(i) to require a functional assessment on the 13th and 19th therapy visit, and at least every 30 days, to determine continued need for therapy services, and to ensure material progress toward goals. The functional assessment does not require a special visit to the patient, but is conducted as part of a regularly scheduled therapy visit. Functional assessments are necessary to demonstrate progress (or the lack thereof) toward therapy goals, and are already part of accepted standards of clinical practice, which include assessing a patient's function on an ongoing basis as part of each visit.

Our current CoPs at §484.55 already require that HHAs "identify the patient's continuing need for home care...". Functional assessments of therapy need guide HHAs in determining whether continued therapy is necessary. Therefore, we believe that the proposed requirements to perform a functional assessment at the 13th and 19th visits, and at least every 30 days, will also not create any burden on HHAs. Rather, we have clarified the minimum timeframes for functional assessments in the coverage regulations. Longstanding policy at §484.55 requires HHAs to document progress toward goals; therefore, we again do not believe that performing or documenting functional assessments at these 3 time-points would create a new burden. Both the functional assessment and its accompanying documentation are already part of existing HHA practices and accepted standards of clinical practice, and are approved under OMB # 0938-1083. Therefore, we do not believe these proposed requirements place any new documentation requirements on HHAs. We also believe that a prudent home health agency would self-impose these requirements in the course of doing business.

Basis for revision to §424.22(a)(1)(i) and §424.22(b)(2) Associated with CY 2010 Final Rule

We have also revised §424.22(a)(1)(i) and §424.22(b)(2) to require a written narrative of clinical justification on the physician certification and recertification for the targeted condition where the patient's overall condition supports a finding that recovery and safety could be ensured only if the care was planned, managed, and evaluated by a registered nurse. We believe that this revision will address HHAs' questions regarding the specific circumstances which would necessitate the need for skilled management and evaluation of the care plan. Additionally, we believe this requirement will be an important step in enhancing the physician accountability and involvement in the patient's plan of care.

As we described above, many Medicaid State Agencies and HHAs contend that there is confusion as to when overall management and evaluation of a care plan constitute a skilled service. They questioned what specific beneficiary underlying conditions, or complications or circumstances would warrant a patient who was receiving unskilled services to need care plan management and evaluation by a registered nurse, thus rendering the care skilled. To clarify for home health agencies what specific circumstances would necessitate the involvement of a registered nurse in the development, management, and evaluation of a patient's care plan when only unskilled services are being provided, we have made additions to the home health certification content requirements as described at §424.22(a)(i) and recertification content requirements at §424.22(b)(2). Specifically, when a patient's underlying condition or complication requires exclusively that a registered nurse ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, we are requiring that the physician include a written narrative on the certification and recertification describing the physician's 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.

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 original 60-day Federal Register notice was published as part of the final rule that published on November 10, 2009 (74 FR 58078).

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)

Revisions to §424.22(a)(1)(i) and §424.22(b)(2)

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.

OMB #	Requirements	# of Respondents	Burden Hours	Total Annual Burden Hours Associate with CY 2010 Final Rule
0938-1083	424.22	345,600	1/12	28,800

The Home Health Prospective Payment System Rate Update for Calendar Year 2011 published on (INSERT DATE) changes the certification requirements for Home Health Agencies. This rule implements a provision of the Patient Protection and Affordable Care Act (PPACA) which was signed by President Obama on March 23, 2010. To implement this provision of PPACA, CMS proposes to revise §424.22(a)(1)(v) such that for initial certifications, prior to a physician signing and dating that certification and thus certifying a patient's eligibility for the Medicare home health benefit, we proposed that the physician responsible for certifying the patient for home health services must document that a face-to-face patient encounter (including through the use of teleheath if appropriate) has occurred no more than 30 days prior to the home health start- of- care date by himself or herself, or by an authorized non-physician practitioner (as specified in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) working in collaboration with or under the supervision of the certifying physician as described above._We are proposing that the certifying physician's documentation of the face-to-face patient encounter be either a separate and distinct area on the certification, or a separate and distinct addendum to the certification, that is easily identifiable and clearly titled.

The burden associated with the documentation requirement for the patient's face-to-face encounter by the physician and certain allowed non-physician practitioners 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 physician or non-physician practitioner to provide the date of the patient encounter and a designated space for the physician or non-physician practitioner 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, 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. Our current regulations only address the physician's signing of the certification and recertification. In this rulemaking, we are proposing to strengthen our regulations at §424.22 to achieve consistency with the proposed timing and documentation of

the face-to-face encounter and to mirror our longstanding manual policy by revising our regulations to make it a requirement that physicians not only sign, but also date certifications and recertifications. Because it has been our longstanding manual policy that physicians sign and date certifications and recertifications, and we are merely making this requirement explicit in our regulations, there is no additional burden to physicians.

HH Face-to-Face Assumptions and Estimates Used Throughout the Impact Analysis Section Associated with CY 2010 Final Rule and CY 2011 Proposed Rule

# 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 Associated with CY 2011 Proposed Rule: 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, 424.22(a)(1)(v)	2,926,420	5	.0833333	243,868	$88.46	$2,287.17	$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 proposed changes to coverage and payment requirements associated with the home health face-to-face physician encounter provision in the CY 2011 home health proposed rule 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 burden associated with the CY 2010 PRA package is estimated to take one physician approximately 5 minutes to meet the written narrative requirement. The frequency of the need for this narrative is estimated to occur in about 5 % of the episodes (or about 345,600 episodes a year), with a total burden of 28,800 annual hours.

The burden from the proposed CY 2011 PRA package is due to statutory changes from the ACA. The burden increase associated with the documentation requirement for the patient's face-to-face encounter by the physician and certain allowed non-physician practitioners includes the one-time burden for each home health agency to design and develop a revised certification form 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 the revised form 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 30 seconds 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, the estimated burden for signing and dating the patient's face-to-face encounter would be 243,868 hours for CY 2011 which is a total increase of 248,584 hours of burden from the CY 2010 PRA package.

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.

C. Collections of Information Employing Statistical Methods

This section does not apply because statistical methods were not used in developing this collection.