Supporting Statement for Paperwork Reduction Act Submissions

A. Background

This information collection package is a request for new information collection requirements as it relates to 42 CFR 424.22; "Requirements for Home Health Services". With this submission, we are creating a new PRA package for home health agencies.

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),(8/4/09 CMM) 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 he 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. .

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).

Basis for Revisions to §409.42(c)(1), 409.44(b), and §424.22

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.

Revisions to §409.42(c)(1)

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).

New paragraph §409.42(c)(1)(i)

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.

New paragraph §409.42(c)(1)(ii)

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.

Change to §409.44(b)

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.

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

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 arerequiring 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 programand 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 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.

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OMB #	Requirements	# of Respondents	Burden Hours	Total Annual Burden Hours
None	424.22	345,600	1/12	28,800

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. Once state survey agencies have completed their surveys and if a final decision to terminate a home health for noncompliance is to be made, such decisions are made by the Central Office and the RO.

15. Changes to Burden

This is a new information collection.

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.