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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 413, 418 and 484

[BPD-469-F]
RIN 0938-AD78

Medicare Program; Medicare Coverage of Home Health Services, Medicare Conditions of Participation, and Home Health Aide Supervision

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This regulation specifies home health aide supervision and duty requirements applicable to all home health agencies (HHAs) and hospices that furnish home health aide services under the Medicare program. It also specifies limitations and exclusions applicable to home health services covered under Medicare. The purpose of this regulation is to clarify Medicare home health policy and to promote consistent administration of the home health benefit.

EFFECTIVE DATE: These regulations are effective on February 21, 1995.

ADDRESSES: For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: John J. Thomas, (410) 966-4623.

SUPPLEMENTARY INFORMATION:

Background

Home health services are furnished to the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services

generally must be furnished by a home health agency (HHA) that participates in the Medicare program, be provided on a visiting basis in the beneficiary's home and include the following:

Part-time or intermittent nursing care furnished by or under the supervision of a registered nurse.

Physical, occupational, or speech 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.

The exception to the requirement that services be furnished in the home includes those services that require the kinds of equipment that cannot be brought to the home and are provided under arrangement with an HHA in a hospital, skilled nursing facility, or rehabilitation agency.

In order for any home health services to be covered under Medicare, specific requirements contained in the Social Security Act (the Act) must be met. Section 1861(m) of the Act requires that the services be furnished under a plan of care established and periodically reviewed by a physician. Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act provide requirements for coverage under Part A and Part B, respectively. Both sections require that a physician certify that the beneficiary is: Under a physician's care; under a plan of care established and periodically reviewed by a physician; confined to the home; and is in need of skilled nursing care on an intermittent basis, physical therapy or speech pathology services, or has a continued need for occupational therapy when eligibility for home health services has been established because of a prior need for intermittent skilled nursing care, speech pathology services, or physical therapy in the current or prior certification period.

Section 1861(m)(4) of the Act provides that before Medicare will cover home health aide services, the home health aides must successfully complete a training and competency evaluation program approved by the Secretary.

Section 1861(dd) of the Act defines hospice care and sets forth the Medicare hospice care provisions. Under section 1861(dd)(1)(D)(i) of the Act, the services of a home health aide are covered as a hospice service only if the aide has successfully completed a training and competency evaluation program that meets the requirements established by the Secretary.

Medicare Home Health Care Initiative

In response to the challenges facing the delivery of home health care, HCFA has recently undertaken the Medicare Home Health Initiative to identify opportunities for improvement in the Medicare home health benefit. In our effort to identify, develop and implement improvements, the initiative takes an integrated approach to the policy, quality assurance, and operational elements of the benefit. To ensure that recommendations for improvement reflect the everyday experience of individuals and organizations involved in home health care, we will include representatives of home health consumers and providers as well as professional organizations, intermediaries, and States (including State Medicaid agencies) in the ongoing development and implementation of improvements to the Medicare home health benefit. The initial meeting between HCFA and these representatives was held on May 16, 17, and 18, 1994. Additional meetings are planned in the coming months.

Although we proposed this rule before the Home Health Initiative began and so developed it independent of the initiative, we consider the rule's provisions to be consistent with the goals of the initiative. A major goal of the initiative is to enhance the effectiveness and efficiency of Medicare home health benefit operational and administrative activities. By clarifying several aspects of Medicare home health policy, this final rule promotes the consistent administration of the home health benefit and therefore constitutes a significant effort to meet this goal.

Provisions of the Proposed Regulations

On September 27, 1991 (56 FR 49154), we proposed to revise home health services regulations contained in 42 CFR part 409, subpart E; part 418, subpart D; and part 484, subpart C. The reader can find all of the details of our proposal in that document. The proposed revisions involved a reorganization of the existing provisions, technical and editorial changes, and the following substantive additions or revisions to the regulations.

A. Home Health Aide Duties and Supervision

We proposed to define the duties of the home health aide as including, but not limited to, hands-on personal care, simple procedures that are an extension of therapy or nursing services, assistance in ambulation or exercise, and assistance in administering medications that are ordinarily self-administered. We also proposed that written patient care instructions for the home health aide had to be prepared by the registered nurse or other appropriate professional responsible for the supervision of the aide.

We proposed to modify the requirements governing supervision of home health aide services to require the following:

+ If the patient is receiving skilled care as well as aide services, the registered nurse or other appropriate professional must make a supervisory visit to the patient's home at least once every 2 weeks. If the aide is an employee of the HHA or hospice, at least one of these visits each month must be made while the aide is providing care to the patient. If the aide is not an employee of the HHA or hospice, the HHA or hospice must perform all supervisory visits of that aide while the aide is providing care to the patient.

+ If the patient is receiving home health aide services but is not receiving skilled care, the supervisory visit must occur not less than once every 62 days.

We proposed to identify the responsibilities of an HHA or hospice that chooses to provide home health aide services under arrangements with another organization as ensuring the overall quality of care provided by the aide, supervising the aide, and ensuring the aide has met the training requirements.

B. Conditions for Payment

Generally, we proposed the following requirements for payment of home health services:

A requirement that the services must be furnished to an eligible beneficiary by, or under arrangements with, an HHA that meets the HHA conditions of participation and has in effect a Medicare provider agreement.

The physician certification and recertification requirements for home health services described in 42 CFR 424.22.

The coverage requirements discussed below.

C. Beneficiary Qualifications for Coverage of Services

We proposed that the beneficiary must be under the care of a physician who establishes the plan of care and that a doctor of podiatric medicine may establish a plan of care under certain circumstances.

D. Requirements for the Plan of Care

We set forth the criteria that would have to be met in order for the plan of care to be considered acceptable. We addressed:
- Those items that must be contained in the plan of care.
- The specificity of the physician's orders for services.
- The timing of review of the plan of care.
- The termination of the plan of care.

E. Requirements for Qualifying Skilled Services To Be Covered and Billable

We described the overall nature of the services that must be furnished for the care to be considered skilled care and the general concepts under which a decision regarding whether the services are reasonable and necessary should be made.

F. Dependent Services Requirements

We proposed that the services listed below would be covered only if the beneficiary had a need for at least one of the qualifying skilled services. We also proposed requirements, based on the statute or long-standing policy, that these services must meet in order to be covered by Medicare.
- Home health aide services.
- Medical social services.
- Occupational therapy.
- Durable medical equipment.
- Medical supplies.
- Services of interns and residents.

G. Allowable Administrative Costs

We proposed that, in general, payment for certain services would be made as an administrative cost.

H. Place of Service Requirements

We proposed, for purposes of Medicare coverage of home health services, that a beneficiary's home is any place in which a beneficiary resides that does not meet the definition of a hospital, skilled nursing facility (SNF), or nursing facility as defined in sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, respectively.

We proposed that for services to be covered in an outpatient setting, they had to require equipment that could not be made available in the beneficiary's home or were services that were furnished while the beneficiary was at the facility to receive services requiring equipment that could not be made available in his or her home. We proposed that an outpatient setting might include a hospital, SNF, rehabilitation center, or outpatient department affiliated with a medical school, with which the HHA has an arrangement to provide services.

I. Number of Visits

We proposed that all Medicare home health services would be covered under Part A if the beneficiary had Part A entitlement and, if the beneficiary had only Part B entitlement, under Part B. We proposed that, if all coverage requirements were met, payment could be made for an unlimited number of covered visits.

J. Excluded Services

We specified that certain items would be excluded from coverage as Medicare home health services:

Drugs and biologicals.

Transportation.

Services that would not be covered as inpatient hospital services. (Note: Although we discussed this proposed provision in the preamble of the proposed rule, it was inadvertently omitted from the proposed regulation text).

Housekeeping services.

Services covered as end stage renal disease services.

Prosthetic devices.

Medical social services provided to family members.

K. Condition of Participation: Clinical Records

We proposed that the discharge summary, including the patient's medical and health status at discharge, must be sent to the attending physician.

Summary of Responses to Comments on the September 27, 1991 Proposed Rule

We received items of correspondence from 144 commenters, including professional organizations and associations, HHAs, public health departments and other State governmental agencies, universities, and individuals. A summary of those comments and our responses follow.

Requirements for Payment (Sec. 409.41)

Comment: One commenter stated that Medicare should provide coverage of home health aide and other services furnished by organizations other than Medicare-approved HHAs.

Response: We are unable to accept this comment. The Act at section 1861(m) defines home health services as specific items and services that are furnished by (or under arrangements with) an HHA (as defined in section 1861(o) of the Act). Therefore, Medicare has no statutory authority to cover any home health service that is not furnished by or under arrangements with a Medicare-approved HHA.

Beneficiary Qualifications for Coverage of Services (Sec. 409.42)

Comment: One commenter stated that the first sentence of Sec. 409.42(b), ``the beneficiary must be under the care of a physician who establishes the plan of care'', should be changed to allow for a patient's treatment by a staff physician.

Response: We do not believe that such a revision is necessary. The requirement that a patient be under the care of a physician who establishes the plan of care does not preclude the patient's treatment by other physicians in addition to the one who establishes the plan of care.

Comment: Several commenters stated that the need for dietician services should be included in Sec. 409.42(c) (which lists the skilled

services necessary to qualify the beneficiary for home health services) and therefore added to those needed skilled services that qualify a beneficiary for coverage of Medicare home health services. (Other commenters wanted this service added to Sec. 409.44 as a covered skilled service.)

Response: Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act establish the eligibility criteria for Medicare coverage of home health services. Because these sections of the Act do not include the need for dietician services with the need for intermittent skilled nursing care, physical therapy, speech pathology services, and continuing occupational therapy as necessary to establish eligibility for Medicare coverage of home health services, we cannot accept these comments.

Comment: One commenter requested we change the terms ``speech therapy'' and ``speech therapist'' to ``speech-language pathology'' and ``speech-language pathologist'' throughout the rule.

Response: We have replaced the term ``speech therapy'' with ``speech-language pathology services'' and the term ``speech therapist'' with ``speech-language pathologist'' throughout this rule. As indicated by the commenter, this revision will ensure that this rule more closely reflects current standards in this area. It is also important to note that the term ``skilled therapist'' in this rule includes speech-language pathologists.

Plan of Care Requirements (Sec. 409.43)

Comment: One commenter requested we clarify that certain services furnished by an HHA that are not related to the treatment of the patient's illness or injury do not require a physician's order.

Response: Section 409.43 establishes plan of care requirements which must be met to obtain Medicare coverage of home health services. Section 409.43 requires all Medicare covered home health services to be furnished under a plan of care established and periodically reviewed by a physician. Noncovered services, such as those that are not related to the treatment of the patient's illness or injury, are not subject to the coverage requirements of this section.

Comment: One commenter requested clarification of the required content of the physician's orders. The commenter was concerned that the intent of the section was to require the physician's order to include a long, narrative description of the services ordered. Another commenter requested clarification of the required specificity of physician's orders for home health aide services.

Response: Section 409.43 does not require that the plan of care include a narrative description of the services ordered. As part of our ongoing efforts to reduce unnecessary paperwork, we have revised this section of the rule to clarify that the plan of care need specify only the medical treatments to be furnished, the discipline that will furnish them, and the frequency at which they will be furnished. Appropriate specificity of medical treatments in the physician's orders would include such orders as ``observe and evaluate surgical site'', ``perform sterile dressing changes'', and, for home health aide services, ``assistance in personal care.'' As practice acts and other laws and regulations govern the actual methods by which these services are performed, it is not necessary to include a description of how to furnish the service in the physician's order. It is also important to note that certain additional plan of care requirements are contained in the Medicare HHA conditions of participation at 42 CFR 484.18.

Comment: One commenter requested that Sec. 409.43(b) be revised to require that orders for therapy services be developed in consultation with the qualified therapist.

Response: Although we believe that the therapist should have input into the development of the physician's orders for therapy services,

this would not be an appropriate revision to the coverage criteria contained in this section as monitoring and compliance efforts would create an additional paperwork burden. This issue is already adequately addressed in the Medicare HHA conditions of participation at 42 CFR 484.18, which requires that ``the therapist and other agency personnel participate in developing the plan of care.''

Comment: One commenter stated that the physician should not be required to order a specific number of visits before care is actually furnished.

Response: Although the physician's order is generally required to specify the number of visits ordered, we recognize that this is not possible in all situations. Therefore, this section allows the physician to order a specific range in the frequency of visits or visits ``as needed'' or ``PRN'' when necessary. We believe that this policy provides the needed flexibility in those cases where a physician cannot anticipate the specific number of visits that will be necessary to meet a patient's needs.

Comment: One commenter suggested that, when a physician orders a range of visits, the lower end of the range should be used as the specific frequency when determining coverage.

Response: We disagree. If the lower end of a range of visits was used as the specific frequency, any services exceeding the lower end, even though they may fall within the range, would not be covered. We believe use of the upper end of the range as the specific frequency affords an HHA the needed flexibility to provide covered services anywhere within the ordered range.

Comment: One commenter stated that it was not practical to require a description of the patient's medical signs and symptoms that would occasion a visit as needed (``PRN'') as well as a specific limit on the number of allowable PRN visits. Another commenter stated that this requirement did not provide HHAs with sufficient flexibility to respond to patient needs.

Response: We disagree with both comments. As we stated in the preamble of the proposed rule, we believe that removing these requirements would allow unreasonable ``open- ended'' orders for care. The intent of this requirement is to allow physicians and HHAs the flexibility needed to effectively serve patients whose need for care cannot be easily predicted, not to give HHAs ``carte blanche'' to provide an unlimited number of visits with no restrictions. The requirement that a physician must describe the medical signs and symptoms that would occasion a visit ensures that the PRN visits are provided only in specific circumstances, such as a plugged urinary catheter or a leaking heparin lock for an IV antibiotic patient. The requirement that the physician impose a specific limit on the number of PRN visits ensures that he or she will remain informed if the patient's need for visits is greater than anticipated. We believe that, by establishing strict parameters in which PRN visits may be furnished, these requirements protect the patient's health and safety while also guarding against Medicare coverage of unreasonable visits.

Comment: One commenter suggested that Sec. 409.43(c) be revised to require the plan of care to be signed by ``a physician'' instead of ``the physician'' to allow for cases in which multiple physicians are providing patient care.

Response: Section 409.43(c) requires only that the plan of care be signed by a physician who meets the certification and recertification requirements of Sec. 424.22, before the bill for services is submitted. This requirement effectively precludes from signing the plan of care a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, the HHA. We do not believe that this requirement restricts the ability of HHA patients to receive care from multiple physicians.

Comment: One commenter suggested that Sec. 409.43(d) be revised to clarify that oral (verbal) orders must be signed and dated by a registered nurse or qualified therapist but need not actually be transcribed by them.

Response: We agree that it would be allowable for a designated member of the HHA staff to receive oral orders over the phone as long as the orders are reviewed, signed, and dated with the date of receipt by a registered nurse or qualified therapist before the services are furnished. We have revised paragraph (d) to require that the ``orders must be put in writing and be signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in Sec. 484.4 of this chapter) responsible for furnishing or supervising the ordered services.'' This revision closely reflects the current policy governing the use of oral orders in the hospital setting (see 42 CFR 482.23(c)(2)). It is also important to note that other Federal or State laws or regulations may restrict the personnel allowed to receive oral orders. To ensure consistency with the Medicare HHA conditions of participation, we have also revised Sec. 484.18(c).

Comment: One commenter stated that the physician should not be required to sign the oral order before the bill for services is submitted to the intermediary. Several commenters complained that physicians are slow to sign these orders in a timely manner because they have no motivation to do so.

Response: We have not revised this requirement. This is a longstanding Medicare requirement that is intended to ensure that the HHA obtains the physician's signature on the oral orders (which confirms that the services were furnished under a physician's order) in a timely manner. We believe that the removal of this requirement would ensure that neither the physician nor the HHA have any motivation to obtain the physician's signature in a timely manner.

Comment: One commenter asked for clarification of whether a plan of care or oral order may be transmitted by facsimile machine.

Response: Yes. The plan of care or oral order may be transmitted by facsimile machine. However, the hard copy of the order with the original signature must be retained and made available to the intermediary, State surveyor, or other authorized personnel upon request.

Comment: One commenter asked that we allow the use of computer-generated ``alternative signatures'' for the physician's signature on the plan of care.

Response: We do not believe that this rule is the appropriate place to establish criteria for the acceptance of computer-generated alternative signatures. However, we do generally support the use of this technology and intend to make revisions to the Medicare HHA and Intermediary Manuals to specify the conditions under which these signatures may be used.

Comment: One commenter stated that the physician should not be required to review the plan of care at least every 62 days. The commenter believed that some patients' need for care can be predicted for more than 62 days, and so the physician's review should only be required when necessary.

Response: We have not accepted this comment. We believe that requiring the physician's review of the plan of care at least once every 62 days protects patient health and safety by ensuring a minimum level of physician oversight. Although it is true that some patients' needs for services are relatively stable, this requirement ensures regular physician review of all patients' care and minimizes the chance of a patient receiving long periods of inappropriate or ineffective care. This requirement is also intended to coordinate with similar physician review requirements contained in Secs. 424.22 and 484.18, thus allowing the HHA to meet the requirements of three regulations

with a single document.

Comment: One commenter stated that the plan of care should not be terminated just because a beneficiary does not receive at least one covered skilled service in a 62 day period.

Response: As explained in this rule, a beneficiary must be in need of either intermittent skilled nursing care or physical therapy, speech-language pathology services, or continuing occupational therapy to qualify for Medicare coverage of home health services. If the physician's plan of care does not order any of these services, we presume that the beneficiary no longer needs any of these skilled services and therefore does not qualify for Medicare home health coverage. However, we understand that some individuals need skilled care at intervals of more than 62 days and so therefore allow coverage of services furnished to beneficiaries who do not require at least one qualifying skilled service in a 62 day period if the physician documents that such an interval without skilled care is appropriate to the treatment of the beneficiary's illness or injury. We do not agree that the beneficiary should be able to continue to receive nonskilled services indefinitely when there is no documented need for a skilled service.

Skilled Service Requirements (Sec. 409.44)

Comment: Several commenters stated that the statement contained in the preamble of the proposed rule regarding the necessity of basing coverage decisions on objective clinical evidence should be included in the text of the final rule.

Response: We agree. We have added a new paragraph (a) to Sec. 409.44 (and redesignated subsequent paragraphs) to include this general statement concerning coverage determinations. We also believe it is important to note that this principle has been explicitly stated in the Medicare HHA Manual as Medicare policy since 1989 and so does not represent a change in the current process of Medicare coverage determinations.

Comment: One commenter stated that the proposed requirements governing skilled nursing care contradict the current principles contained in the Medicare HHA Manual.

Response: We disagree. The requirements of this section are based on section 205.1(A) of the Medicare HHA Manual, which is entitled ``General Principles Governing Reasonable and Necessary Skilled Nursing Care.'' The requirements of this rule closely reflect the manual provisions and in many ways are identical.

Comment: One commenter suggested that this section be revised to include a reference to the skilled nursing requirements of 42 CFR 409.33, which provides examples of skilled nursing care for purposes of Medicare coverage of posthospital skilled nursing facility care.

Response: We agree and have added a cross-reference to paragraphs (a) and (b) of Sec. 409.33.

Comment: One commenter stated that this section should specify that teaching and training are covered skilled nursing services. Another commenter stated that this section should specifically note that the management and evaluation of a care plan is a covered skilled nursing service.

Response: By adding the cross-reference explained in the previous response, Sec. 409.44 now incorporates the description of skilled nursing care contained in Sec. 409.33. Section 409.33 includes patient education services and the management and evaluation of a care plan as examples of skilled nursing care.

Comment: Several commenters expressed concern about Medicare's policy that a service that can safely and effectively be performed by the average nonmedical person without the supervision of a licensed

nurse cannot be considered a skilled nursing service. The commenters specifically disagreed with the preamble's example of a nonskilled service that described a patient who could not self-administer eye drops that are normally self-administrable. The commenters believed that the absence of a caregiver to administer the eyedrops made the administration of the eyedrops a skilled service.

Response: Our policy that a nonskilled service does not become a skilled service simply because there is no competent person to perform it is intended to protect Medicare from paying skilled personnel (at a skilled rate) for furnishing nonskilled services. In the example described above, the absence of a caregiver to administer the eyedrops does not make their administration a skilled service. Therefore, this rule at Sec. 409.44(b)(1)(iv) states that ``if the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.'' This clear statement represents no change from the longstanding Medicare policy that is currently contained in the Medicare HHA Manual at Sec. 205.1(A)(2) and (B)(4)(c).

Comment: Several commenters requested clarification of Medicare coverage of skilled nursing care following cataract surgery.

Response: Medicare coverage of skilled nursing care furnished to beneficiaries who have recently undergone cataract surgery is based on the same policies governing Medicare home health coverage of skilled nursing care furnished to any beneficiary. If, for example, the patient's unique medical condition is such that the skills of a nurse are required to observe and assess his or her condition or furnish additional teaching of a medication regimen or safety precautions, these services would be covered. It is important to note, however, that the routine initial teaching of post-cataract medication administration and post-operative safety precautions that is needed by any individual having cataract surgery is routinely furnished by ophthalmologists as part of their care of cataract patients. Therefore, it is not considered reasonable and necessary for a HHA to duplicate such services.

Comment: One commenter requested that we remove the current requirement that psychiatric nursing services be furnished under a plan of care established and periodically reviewed by a psychiatrist (see section 205.1(B)(15) of the Medicare HHA Manual). The commenter believed that this requirement made it difficult for some beneficiaries who do not have access to a psychiatrist to receive needed care from a psychiatrically trained nurse. The commenter also requested that we include several examples of covered psychiatric nursing care.

Response: With regard to the requirement that a psychiatrist establish and review plans of care for psychiatric nursing services, we agree with the commenter's concerns. We have not included a similar requirement in this rule and intend to revise the requirements contained in the HHA Manual. We do not believe that this rule is the appropriate place to include specific examples of skilled nursing care. However, we do intend to include several examples of covered psychiatric nursing services in the revisions to the Medicare HHA Manual that will follow the publication of this rule.

Comment: One commenter requested that the phrase ``standards of medical practice'' in proposed Sec. 409.44(b)(2)(i) of this section be revised to read ``standards of practice'' to recognize the standards that have been developed by therapy professionals.

Response: We have not accepted this comment. We do not believe that the phrase ``standards of medical practice'' excludes those standards developed by therapy professionals. We require covered therapy services also to be considered specific, safe, and effective treatment under the appropriate therapy standards of practice.

Comment: One commenter stated that the coverage requirements of

proposed Sec. 409.44(b)(2)(ii) (which describes the level of complexity and sophistication of covered services) are too restrictive. The commenter believed that Medicare should cover any services that ``fall within the scope of the licensed professional.''

Response: We do not agree with the commenter. We believe that such a vague and general policy would result in Medicare paying for many services that do not necessarily require the skills of a licensed therapist to be performed safely and effectively. For example, assisting a patient with simple transfers could be performed safely and effectively by a physical therapist, but it should not be covered as a skilled therapy service because it could also be furnished safely and effectively by a home health aide. We believe that the provisions of this paragraph ensure that Medicare will pay only for those services which require the skills of a licensed therapist to be performed safely and effectively.

Comment: One commenter stated that the requirement of Sec. 409.44(c)(2)(iii) that ``there must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time * * *'' is too vague. The commenter specifically recommended that we delete the word ``materially'' from the paragraph.

Response: We have not accepted this comment. We consider ``material'' improvement to be improvement to a significant degree or extent. This requirement ensures that Medicare will cover only those therapy services that are actually contributing to the treatment of the patient's illness or injury. Such a requirement cannot be completely precise in its application to all possible situations and its application does depend somewhat on the discretion of the intermediary. However, we believe that the requirement of this paragraph is reasonable and understandable. We also point out that this is a longstanding policy that is currently contained in the Medicare HHA Manual at section 205.2(A)(5).

Comment: One commenter stated that paragraph (b) of proposed Sec. 409.44 should be revised to recognize the medical necessity of extended therapy in certain cases and of active therapy furnished to patients whose health is declining in certain cases.

Response: We do not believe that such a revision is necessary. Paragraph (c) (paragraph (b) in the proposed rule) states that Medicare will pay for the services of a therapist when his or her skills are necessary for the safe and effective performance of a maintenance program. This policy clearly recognizes that, in certain cases, an extended maintenance program can be considered medically necessary.

We also believe that active therapy for a beneficiary whose health is declining can be covered. The new paragraph (a) of this section that we have added in this final rule specifies that the intermediary's decision on whether care is reasonable and necessary must be based on objective clinical evidence and the beneficiary's unique need for care. Therefore, this rule specifically prohibits claims decisions based on general inferences about patients with similar diagnoses, which means that it would be inappropriate for an intermediary to deny therapy services solely on the basis that they were furnished over a long period of time or to a patient whose general health status is in decline.

Comment: One commenter stated that we should require that the expectation that the beneficiary's condition will materially improve be based on the therapist's assessment of the patient's rehabilitation potential and the physician's assessment of the patient's unique medical condition. (We proposed only to require the physician's assessment.)

Response: We believe that such a revision would not be appropriate. Our policy concerning the physician's role in determining the patient's

need for care is based on section 1861(m) of the Act, which requires covered home health services to be furnished under a plan of care established and periodically reviewed by a physician, and sections 1814(a)(2)(C) and 1835(a)(2)(A), which require qualified Medicare home health beneficiaries to be under the care of a physician and receiving services under a plan of care established and periodically reviewed by a physician. Because the law specifically assigns these responsibilities to the physician, we do not believe that it would be appropriate to shift the responsibility for assessment of the patient to an individual other than the physician. In addition, we believe that the therapist's role in establishing the plan of care is adequately protected by the Medicare HHA conditions of participation at 42 CFR 484.18(a), which specifically requires the consultation and participation of the therapist (as well as other HHA staff) in the development of the plan of care.

Dependent Services Requirements (Sec. 409.45)

Comment: Several commenters stated that Medicare should cover home health aide and medical social services furnished after the final qualifying skilled visit.

Response: The Act at sections 1814(a)(2)(C) and 1835(a)(2)(A) specifically requires that a beneficiary be in need of physical therapy, speech pathology services, continuing occupational therapy, or intermittent skilled nursing care to be eligible for Medicare coverage of home health services. Because a patient who has received his or her last qualifying service can no longer be considered in need of that service, Medicare cannot pay for any home health aide or medical social services furnished that patient after the final qualifying visit. We have revised paragraph (a) of Sec. 409.45 to clarify that dependent services furnished after the final qualifying service are not covered, except when the dependent service was not followed by a qualifying service due to an unanticipated event such as the unexpected inpatient admission or death of the beneficiary.

Comment: One commenter stated that the phrase ``repetitive speech routines to support speech therapy'' in Sec. 409.45(b)(1)(iv) should be replaced with ``functional communication skills and opportunities to support speech-language pathology services.''

Response: We have revised this phrase to refer to ``repetitive practice of functional communication skills to support speech-language pathology services.'' We believe that this revision addresses the commenter's concern and will be readily understood by providers, intermediaries, and others.

Comment: One commenter stated that Sec. 409.45 should be revised to include respite care for a beneficiary's caregiver as a covered home health aide service.

Response: We have not accepted this comment. An individual who requires covered services--such as skilled nursing care--may receive them when the need for the services arises because a caregiver who ordinarily provides them is temporarily unavailable. In this context, the services are covered home health services even though one result may be respite for the caregiver. On the other hand, the Act at section 1862(a)(1)(A) excludes any service that is not ``reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member'' from Medicare coverage. ``Respite care'' that does not represent actual treatment of the beneficiary's illness or injury, but primarily consists of noncovered care provided in order to relieve the beneficiary's caregiver, would fall under the statutory exclusion. We have no statutory authority to cover respite care as a home health aide service. To make this long-standing Medicare policy clear,

Sec. 409.45(b)(1) of this section specifically states that a covered home health aide visit must be for the provision of hands-on personal care to the beneficiary or for services that are needed to maintain the beneficiary's health or to facilitate treatment of the beneficiary's illness or injury.

Comment: One commenter objected to Sec. 409.45(b)(3)(iii), which requires that covered home health aide services ``be of a type that there is no willing or able caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual.'' The commenter believes that this could lead to abuse of the Medicare program by beneficiaries who seek to receive home health aide services by refusing to accept the services of an able caregiver.

Response: We have not revised this requirement. It has long been Medicare policy to cover services without regard to whether there is someone in the home who could furnish them. This policy is described in section 203.2 of the HHA Manual, which states:

Where the Medicare criteria for coverage of home health services are met, beneficiaries are entitled by law to coverage of reasonable and necessary home health services. Therefore, a beneficiary is entitled to have the costs of reasonable and necessary services reimbursed by Medicare without regard to whether there is someone in the home available to furnish them.

In those cases in which the beneficiary refuses to accept the services of an available caregiver, or when a caregiver refuses to furnish needed care, it is not appropriate for Medicare to coerce those individuals into providing or receiving the services under circumstances to which they object. Of course, if a caregiver is furnishing necessary services, Medicare will not pay for a home health aide to furnish duplicative services. In addition, although we appreciate the commenter's concern, we have no evidence of widespread abuse of this long-standing policy.

Comment: One commenter suggested that we not require medical social services to be furnished under physician orders. The commenter believes that physicians are not qualified to determine a patient's need for medical social services.

Response: Section 1861(m) of the Act requires that all covered home health services be furnished under a plan of care established and periodically reviewed by a physician. In addition, this section of the Act specifically defines ``medical social services under the direction of a physician'' as a covered home health service. Therefore, we cannot accept the commenter's suggestion.

Comment: One commenter requested that we clarify what constitutes a social or emotional problem that is an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

Response: A social or emotional problem that impedes (or is expected to impede) a beneficiary's medical treatment is a problem which may obstruct or inhibit the effective treatment of the beneficiary's medical condition. Examples are an emotional problem that causes the beneficiary to neglect his or her medication regimen and a social problem, such as a hostile family situation or an extremely limited income, that results in the beneficiary receiving inadequate nutrition or personal assistance. The Medicare HHA Manual at Sec. 206.3 provides several examples of covered medical social services provided to beneficiaries with such problems.

Comment: Several commenters stated that this section should be revised to allow Medicare coverage of medical social services furnished to a beneficiary's family when such services are necessary to resolve

an impediment to the beneficiary's medical treatment.

Response: We agree with the commenters and have revised Sec. 409.45(c)(2) accordingly to allow for Medicare coverage of medical social services furnished on a short-term basis to a beneficiary's family member or caregiver when it can be demonstrated that a brief intervention (that is, two or three visits) by the medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

We believe that medical social services furnished to a beneficiary's family member or caregiver in these circumstances will enhance the effectiveness of the treatment of the beneficiary's illness or injury. In those cases where a family member or caregiver is directly impeding the beneficiary's medical treatment or rate of recovery (for example, by failing to provide necessary care or by engaging in abusive neglectful behavior), we believe that short-term medical social services furnished to the caregiver or family member for the purpose of removing that impediment will greatly benefit the home health patient by enhancing the effectiveness of his or her medical treatment and, ultimately, the rate and level of his or her recovery. We also expect that, in these circumstances, the effective use of short-term medical social services will result in a reduction in the beneficiary's need for other home health services (such as skilled nursing care to observe and assess the patient's treatment and progress). In some cases, these services may also prevent a costly inpatient stay by the beneficiary necessitated by his or her unhealthy or unsafe home environment.

We also note that Medicare currently covers family counseling services furnished by a physician to a beneficiary's family when the primary purpose is the treatment of the beneficiary's condition and not the treatment of the family member's problems (see Sec. 35-14 of the Medicare Coverage Issues Manual). We believe that the services of a medical social worker furnished to a beneficiary's family member under similar circumstances would also be of value.

In addition, this coverage is consistent with our long-standing policy regarding the coverage of home health skilled nursing visits for purposes of teaching and training family members or caregivers. Medicare has long covered a limited number of skilled nursing visits for teaching and training family members where the teaching and training is appropriate to prepare the family member to furnish treatment or support for the beneficiary's functional loss, illness or injury. Again, as with the physician counseling, Medicare covers these visits.

It is important to emphasize that this revision is intended to cover medical social services furnished to a family member or caregiver only when a brief intervention will resolve a problem which clearly and directly impedes the beneficiary's medical treatment. To be considered ``clear and direct'' the behavior or actions of the family member or caregiver must plainly obstruct, contravene, or prevent the patient's medical treatment or rate of recovery. The HHA is responsible for demonstrating in its documentation that the problem is a clear and direct impediment to the treatment of the beneficiary's medical condition or rate of recovery. Medical social services furnished to address general problems that do not clearly and directly impede the beneficiary's treatment or rate of recovery as well as long-term social services furnished to family members, such as ongoing alcohol counseling, are not covered. Because we have limited coverage to medical social services to address only clear and direct impediments on a short-term basis, it is our expectation that medical social services furnished to family members or caregivers should require only a brief intervention on the part of the social worker, which should rarely

exceed two or three visits. We intend to include an example of covered medical social services furnished to a family member in the Medicare HHA Manual. We have also revised in this final rule the paragraph (g) that we had proposed to add to Sec. 409.49. That paragraph will now exclude from Medicare coverage medical social services furnished to family members, except as provided in Sec. 409.45(c)(2).

Comment: One commenter objected to this section's requirement that covered medical social services must be necessary to resolve social or emotional problems that are expected to be an impediment to the treatment of the beneficiary's medical condition or to his or her rate of recovery. The commenter stated that the services of a social worker may address a wide range of difficulties in addition to those that present an impediment to the treatment of the beneficiary's medical condition.

Response: The Act at section 1861(m) specifically defines medical social services as a covered home health service. In addition, section 1862(a)(1)(A) of the Act excludes from Medicare coverage any service that is not reasonable and necessary for the diagnosis or treatment of the patient's illness or injury. Therefore, Medicare is limited to covering those social services that are provided to treat the patient's medical condition; that is, they are directed at resolving impediments to the treatment of the patient's illness or injury. Although we agree that professional social workers are qualified to address a wide range of problems beyond those that may affect the treatment of the patient's medical condition, we do not agree that Medicare should cover such services.

Comment: Several commenters objected to the provision that covered medical social services must require the skills of a social worker or a social work assistant to be performed safely and effectively.

Response: We do not believe that this requirement is unreasonable. It would not be proper for Medicare to pay a social worker to perform services that do not require his or her unique skills. It is important to note that this is a longstanding coverage requirement that also applies to skilled nursing and therapy services (see Secs. 409.44(b)(1)(ii) and (c)(2)(ii)). This longstanding requirement is intended to protect Medicare from making payment to a skilled professional for services that could have been furnished by the average nonmedical person.

Comment: One commenter suggested that paragraph (e) be revised to describe Medicare coverage of certain intravenous pump supplies specifically as it is described in section 3113.4 of the Medicare Intermediary Manual.

Response: The manual section to which the commenter refers describes Medicare Part B coverage of durable medical equipment (DME) and related supplies. We do not believe that the suggested revision is necessary because paragraph (e) of this section specifically provides for Medicare coverage of DME under the home health benefit identical to its coverage under Part B. Therefore, all policy relating to Part B coverage of DME applies to home health DME coverage, not just the policy contained in section 3113.4 of the Intermediary Manual. We have chosen not to include the extensive manual provisions on Part B DME coverage in this rule, but we have cross-referenced paragraph (e) with 42 CFR 410.38, which contains the regulations describing the scope and conditions of payment for DME under Part B. We have not included the manual provisions in this rule because we believe that Sec. 410.38 (to which this section refers) provides an adequate description of Medicare DME coverage and because the extensive and detailed nature of the manual provisions on DME coverage make them best suited for inclusion in the appropriate manuals but inappropriate for inclusion in this rule. We also note that Sec. 220 of the Medicare HHA Manual describes this coverage in depth.

Comment: One commenter stated that HCFA should issue a list of Medicare-covered medical supplies.

Response: We do not issue a list of covered medical supplies because it is not feasible to compile and maintain such a list in a timely and comprehensive manner. Also, in some cases, Medicare coverage of a certain item may depend on the circumstances in which it is used (such as skin lotion or shampoo), and so a list would not adequately provide for all possible coverage. Therefore, we define (in both this rule and in the Medicare HHA Manual) the criteria for Medicare coverage of medical supplies and rely on the intermediary to apply those criteria on a case-by-case basis.

Comment: One commenter informed us that the Council on Medical Education of the American Medical Association, to which we referred in Sec. 409.45(g), is now known as the Accreditation Council for Graduate Medical Education.

Response: We have made the appropriate revision to paragraph (g).

Allowable Administrative Costs (Sec. 409.46)

Comment: One commenter stated that Sec. 409.46(a) should be revised to allow for Medicare coverage of skilled nursing services furnished without a physician's orders during the initial evaluation visit.

Response: In addition to establishing other requirements, section 1861(m) of the Act defines covered home health services as items and services furnished under a plan of care established and periodically reviewed by a physician. Therefore, there is no statutory authority for Medicare coverage of services that have not been ordered by a physician. If the nurse performing the evaluation visit finds the beneficiary to be in need of immediate care, he or she may obtain verbal orders for care from a physician at that time and then proceed to furnish the ordered care. In this circumstance, the initial evaluation visit would then become a Medicare-covered skilled nursing visit.

Comment: One commenter stated that visits by registered nurses or other qualified professionals for the supervision of home health aides should be considered a home health aide cost rather than an allowable administrative cost.

Response: Because the cost of the supervisory visit is associated with providing an administrative service (that is, compliance with the requirements of the Medicare HHA conditions of participation at 42 CFR 484.36) and not a home health aide service, the costs associated with the provision of the required supervisory visits is an allowable administrative cost. We have also added a new Sec. 413.125 in this final rule to refer to the rules on the allowability of certain costs in this section as well as Sec. 409.49(b).

Comment: One commenter suggested that Sec. 409.46(c) be revised to specify that only skilled nurses or physical therapists with special training in respiratory care be allowed to furnish respiratory therapy services.

Response: We have not accepted this comment for two reasons. First, the purpose of this section is to describe certain services that are allowable administrative costs, not to establish requirements for coverage of skilled nursing or physical therapy services; therefore, such a revision would not be appropriate to this section. Second, we do not believe that such a revision is necessary because State practice acts and professional standards of practice generally regulate the services that can be provided by nurses and therapists, thus preventing nurses or therapists from furnishing services they are not qualified to provide.

Place of Service Requirements (Sec. 409.47)

Comment: One commenter suggested that this section be revised to reflect the place of service provisions formerly at Sec. 409.42(e)(1).

Response: We have accepted this comment. We have revised this section to reflect the specific provisions of section 1861(m)(7) of the Act and previous regulations at Sec. 409.42(e) more closely. As stated in the revised Sec. 409.47(b), an outpatient setting may include a hospital, a SNF or a rehabilitation center with which the HHA has an arrangement in accordance with Sec. 484.14(h) of this chapter. We believe that this revised requirement, by duplicating the provisions of section 1861(m) of the Act, more closely reflects the original congressional intent to restrict home health coverage of outpatient services to only a few specific outpatient facilities and thus ensure that home health services would be primarily provided in the homes of the beneficiaries.

It has also been brought to our attention that the definition of a beneficiary's home at proposed Sec. 409.47(a) and the definition of ``confined to the home'' at proposed Sec. 409.42(a) were not entirely consistent. We have revised Sec. 409.42(a) so that both sections define a beneficiary's home for purposes of Medicare home health coverage as any place in which the beneficiary resides that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, respectively.

Comment: One commenter suggested that the place of service requirements contained in Sec. 409.47(b) be expanded to allow Medicare home health coverage of outpatient services furnished in a variety of settings, such as general outpatient clinics and adult day care facilities.

Response: As we explained in the previous response, the Act specifically allows Medicare coverage of outpatient home health services furnished in a hospital, SNF, or rehabilitation center. We have revised paragraph (b) to reflect the statutory provision. We have not expanded the list of allowable outpatient settings because such a revision would not be consistent with the plain language of the statute. Also, it is important to note that section 1861(m)(7)(A) of the Act provides for coverage of outpatient home health services only when the beneficiary requires a service which ``involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual'' in his or her home. This means that Medicare coverage of outpatient home health services is available only when the primary service cannot be furnished in the home, not merely when it is more convenient to the HHA or beneficiary to provide the service in an outpatient setting. Because coverage of outpatient home health services is available only in such specific circumstances, we believe that the statutory limitation of the services to certain specific facilities is appropriate and does not restrict a beneficiary's access to covered home health outpatient care.

Visits (Sec. 409.48)

Comment: One commenter requested clarification of Medicare coverage when a nurse provides a skilled nursing service and a home health aide service in the course of a single visit. The commenter suggested that the HHA should receive two payments for this visit: one payment for a skilled nursing visit and one for a home health aide visit.

Response: If a nurse furnishes several services that fall within the normal scope of a nurse's practice in the course of a single visit, that constitutes only one visit. Because the visit involved only a single nurse providing home health services during the course of a single visit, the fact that the nurse also provided incidental unskilled services (which can be safely and effectively provided by a

licensed nurse) in addition to the skilled nursing care does not mean that the service could be covered as two visits. We consider this situation to involve only a single episode of personal contact between the HHA staff and the beneficiary and, therefore, covered only as a single visit under the requirements of Sec. 409.48(c).

Comment: One commenter requested clarification of Medicare coverage when two individuals are needed to provide a service. The commenter specifically cited a situation in which a nurse and a home health aide are required to furnish a service.

Response: As stated in Sec. 409.48(c)(3) of this section, Medicare will pay for two visits when two individuals are needed to furnish a service (e.g., a bath, wound care, or a certain exercise). Because each patient's situation is unique, we have not established a specific guideline for which combinations of HHA personnel can furnish services that are covered as two visits. The personnel, however, must be appropriate for the service to be performed (for example, it would not require the services of two licensed nurses to give a routine bath to a heavy beneficiary). Although coverage of these services does not require the HHA to submit any additional documentation, the clinical notes should describe why it is necessary for two individuals to furnish the service (patient's weight, nature of required equipment, etc.).

Comment: One commenter opposed the coverage of two visits when the HHA staff cannot provide the reasonable and necessary care in the course of a single visit but remain in the beneficiary's home between the provision of the services. The commenter stated that claims for coverage in this situation would be too difficult for the intermediary to review. Another commenter requested that we rescind this coverage until its impact can be studied.

Response: We have not accepted either of these comments. We believe that, in those situations in which the HHA cannot provide the necessary services in the course of a single visit (e.g., wound dressing changes), it is fair and reasonable to cover two separate visits even though the individual furnishing the care has remained in the home between visits (e.g., to provide companionship or other non-covered care). Abandonment of this policy would simply result in HHA staff leaving the home for a token period of time or having a different HHA staff member provide the second service to create an artificial ``second visit.'' Although coverage of these visits may be more demanding for the intermediary to review, the removal of this coverage would inevitably result in HHAs allocating staff less efficiently to secure coverage of two visits. In summary, if the two services cannot feasibly be provided in a single visit, we do not believe what the provider does between those services is relevant to the coverage decision. With regard to delaying implementation of this coverage, Medicare has covered two visits in this situation for some time without discernible effect. This rule codifies current coverage.

Excluded Services (Sec. 409.49)

Comment: One commenter stated that the Medicare home health benefit should cover drugs and biologicals furnished in the home.

Response: We cannot accept this comment because section 1861(m)(5) of the Act specifically excludes drugs and biologicals from Medicare home health coverage.

Comment: One commenter noted that the regulations text in the proposed rule omitted paragraph (c) of Sec. 409.49.

Response: The proposed rule did inadvertently omit paragraph (c) of this section from the regulations text, although the provisions of paragraph (c) were described in the preamble. This final rule includes paragraph (c), which excludes from home health coverage services which

would not be covered if furnished as hospital inpatient services. We have specified this exclusion because the unnumbered material in section 1861(m) of the Act following paragraph (m)(7) specifically precludes home health coverage of any service that would not be covered as an inpatient hospital service.

Comment: One commenter stated that exclusion from coverage of housekeeping services is too restrictive.

Response: We do not agree. It is important to note that Sec. 409.49(d) excludes only those services whose sole purpose is to allow the beneficiary to continue to reside in his or her home. If a home health aide performs some light housekeeping incidental to providing a covered home health aide service, that visit would not be excluded from coverage. However, a visit for the sole purpose of providing housekeeping services would not be covered, as these services are not related to the treatment of the beneficiary's illness or injury. As we stated in the preamble of the proposed rule, this does not represent any change from current Medicare policy and would not affect the coverage of home health aide services that are essential for healthcare, such as bathroom disinfection and the cleaning of soiled sheets. Also, it is important to note that this exclusion applies to Medicare coverage of aide services under the home health benefit and has no impact on coverage of ``homemaker'' services furnished under the Medicare hospice benefit. ``Homemaker'' services, which we consider to be identical to housekeeping services, are specifically mentioned as a covered hospice service in 42 CFR 418.202(g).

Comment: Several commenters asked that we clarify Medicare coverage of home health services furnished to end stage renal disease (ESRD) patients. One commenter specifically requested clarification of Medicare coverage of a home health nursing visit to furnish wound care related to an abandoned shunt site.

Response: Because Medicare's composite rate payment to an ESRD facility is intended to subsume payment for all dialysis-related services, any service directly related to a beneficiary's dialysis is covered as a dialysis service and not as a home health service. Home health services that are not related to an ESRD beneficiary's dialysis, however, can be covered under the home health benefit if all requirements are met (for example, the beneficiary is homebound). Only those services which are directly related to the beneficiary's dialysis (and not to other aspects of renal disease) are excluded by this paragraph. Because wound care for an abandoned shunt site is not directly related to the beneficiary's dialysis, a nursing visit to furnish such care to a qualified Medicare home health beneficiary would be covered.

Comment: One commenter stated that the reference to Sec. 410.36 in paragraph (f) appears to exclude coverage of wound supplies and intravenous maintenance supplies.

Response: Paragraph (f) excludes from coverage only those items which meet the requirements of Sec. 410.36(b) for prosthetic devices. That is, prosthetic devices that replace all or part of a body organ (with the exception of catheters, catheter supplies, ostomy bags, and bags relating to ostomy care) are excluded from coverage under the home health benefit. Section 1861(m) of the Act indicates that medical supplies and durable medical equipment are covered home health services. Since prosthetic devices are not also listed in section 1861(m), they cannot be covered as home health services. Items described in Sec. 410.36(a), such as surgical dressings, are not excluded by this paragraph. Any item that meets the requirements for coverage contained in Sec. 409.45(f) of this rule as medical supplies may be covered as a home health service.

Condition of Participation: Home Health Aide Services (Sec. 484.36)

Comment: Several commenters stated that the current requirement that home health aides must receive at least 12 hours of in-service training each calendar year is overly burdensome. The commenters did not protest the required number of training hours but found the requirement that the training be furnished within each calendar year to present burdensome scheduling problems. The commenters said these scheduling problems were particularly difficult in the cases of home health aides who were hired late in the calendar year and therefore were obligated to complete the 12 hours of training in a relatively short period of time.

Response: We agree with the commenters that this requirement would be overly burdensome and have revised proposed Sec. 484.36(b)(2)(iii) to require each aide to receive at least 12 hours of in-service training per 12 month period. Without the requirement that the training be received in each calendar year, this provision will allow HHAs a full 12 months to provide the required in-service training to newly hired home health aides. The revised requirement will also allow HHAs greater flexibility in scheduling in-service training programs.

Comment: One commenter stated that the provision of Sec. 484.36(c) requiring the registered nurse to assign the home health aide to a specific patient reduces the HHA's scheduling flexibility and ability to send a substitute aide in the event of sickness or other unforeseen circumstances.

Response: This requirement represents no change from the current requirements of this section. Although we understand that this requirement may slightly reduce the HHA's scheduling flexibility, we believe that the benefits to be gained by its encouragement of consistency in care and familiarity between patient and home health aide far outweighs any reduction in scheduling flexibility. This requirement does not prevent the assignment of more than one aide to a patient, and we certainly do not intend it to preclude the use of a substitute aide when illness or other unforseen circumstances prevents the regularly scheduled aide from providing services.

Comment: One commenter stated that a licensed practical nurse (LPN) should be allowed to perform the required home health aide supervisory visit.

Response: We do not agree. We believe that the more extensive educational background of a registered nurse (RN) makes the RN better equipped to assess the care provided by the home health aide as well as the total effect of the care on the patient's condition. Therefore, we believe that it is in the best interest of the patient's health and safety to require that supervisory visits be performed by an RN. It has long been Medicare policy that the RN's extensive professional training uniquely qualifies him or her to perform evaluation and supervisory functions. This recognition of the RN's qualifications is represented not only in this section but in Sec. 484.30, which describes skilled nursing services, Sec. 484.16, which describes the group of professional personnel, and Sec. 484.14(d), which requires therapeutic services to be furnished under the supervision of a physician or RN.

Comment: One commenter opposed the requirement that a supervisory visit be performed no less frequently than every two weeks as costly to the HHA and unnecessary because these patients are regularly seen by a nurse or therapist who likely performs a basic assessment of the care furnished by the home health aide anyway.

Response: We disagree with the commenter. If the patient is receiving skilled care from a registered nurse or therapist on a biweekly basis, then the professional can easily perform the required supervisory visit during the course of his or her visit to furnish covered skilled care. Therefore, we believe that patients in the situation described by the commenter present little cost or difficulty

to an HHA scheduling supervisory visits. Not all patients, however, receive skilled nursing or therapy services on such a regular basis. When a patient is receiving skilled nursing or therapy services, we believe that it is in the best interest of the patient to require the registered nurse or appropriate therapist to supervise and assess the care furnished by the home health aide on a biweekly basis. This supervisory visit ensures that the aide services will be regularly assessed to ensure that they are furnished properly and of benefit to the treatment of the patient's illness or injury.

Comment: Many commenters oppose the proposed provision in Sec. 484.36(d)(2)(i), which would have required at least one supervisory visit per month to occur while the aide is furnishing services if the patient is receiving one or more skilled services. Many commenters also oppose the proposed provision in paragraph (d)(2)(ii), which would have required all supervisory visits to occur while the aide is furnishing services when the aide is not employed directly by the HHA.

Response: We have accepted these comments and are not including these proposed supervisory requirements contained in Sec. 484.36(d)(2)(i) and (ii) in the final rule. We have concluded that the improvement in the quality of home health aide services that has occurred as a result of the home health aide training and competency evaluation requirements implemented in 1990, as well as the increase in patient participation in care that has resulted from the recently implemented patient rights requirements of Sec. 484.10, make the proposed requirements for direct aide supervision unnecessary. These requirements were proposed in response to a study published by the Office of the Inspector General in September 1987. (``Home Health Aide Services for Medicare Patients'', OA1-02-86-00010, September 1987.) Since the time this study was completed, however, we have instituted the training and evaluation requirements referred to above as well as annual in-service training and performance review requirements. We believe that these requirements have significantly improved the quality and oversight of home health aide services. In addition, the institution of patient rights requirements has given home health patients a more comprehensive knowledge of their rights regarding care planning and provision. This, in effect, lets the patient play a greater role in the oversight of the care he or she receives.

Many commenters stated that arranging for the provision of the proposed supervisory requirements would impose significant burdens and costs associated with scheduling, travel, and the inefficient allocation of nursing resources. Many commenters also stated that the joint visits would be of limited value because many patients are reluctant to voice concerns or complaints in the presence of the home health aide (preferring to speak with the nurse privately in person or by telephone). These legitimate and practical concerns have persuaded us that the value to be gained by the proposed requirements does not merit the burden which they would impose on HHAs. Because of the progress we have already made in our efforts to ensure the high quality of home health aide services furnished by Medicare-approved HHAs, we do not believe that the advantages of the proposed requirements justify their associated cost and burden. Therefore, this final rule does not contain the requirements.

Comment: Two commenters stated that the required supervisory visit by a registered nurse every 62 days when the non-Medicare patient is receiving home health aide services but no skilled nursing care or physical, speech, or occupational therapy is too infrequent. One commenter believes that the required frequency of supervisory visits does not provide adequate oversight of home health aide services.

Response: We disagree. We believe that these non-Medicare patients who are not receiving skilled nursing care, physical or occupational

therapy, or speech-language pathology services are not as ill as those who are receiving skilled services and therefore are at less risk of medical problems or complications that could occur during the course of receiving home health aide services. Because these patients are less ill, and therefore receiving home health aide care that is likely to be more custodial in nature, we believe that it is appropriate to require a lower frequency of supervision. Due to the lower frequency of these visits, we have specifically required them to occur while the aide is furnishing services so that the nurse can assess the aide's actual provision of care as well as the general condition of the patient. Also, we are requiring the on-site supervisory visit (which applies only to non- Medicare patients) at this frequency to conform Federal requirements that apply to HHAs that participate in Medicare with the licensure requirements of many States, thus enabling many HHAs to meet the administrative requirements of two bodies with a single visit.

Condition of Participation: Clinical Records (Sec. 409.48)

Comment: Several commenters expressed concern that the proposed requirement that discharge summaries be sent to the attending physician will increase the flow of unwanted paperwork into physicians' offices. One commenter suggested that we require HHAs to inform the attending physician of the availability of the discharge summary.

Response: We understand the commenters' concern and have accepted the suggestion. We have revised Sec. 484.48 to require the HHA to inform the attending physician of the availability of a discharge summary and send it to him or her upon request. This requirement will allow physicians to remain informed of the care furnished to their patients while minimizing the amount of unwanted paperwork being sent to physicians' offices. We would also like to clarify that the discharge summary need not be a separate piece of paper and could be incorporated into the routine summary reports already furnished to the physician.

Comment: One commenter stated that the discharge summary requirement could not be implemented without clearance under the Paperwork Reduction Act.

Response: We do not agree with the commenter. The requirement that HHAs maintain a discharge summary for each patient is not new. Section 484.48 has long required the HHA to include a discharge summary in the patient's clinical record. This rule does not impose any additional paperwork requirements. It only requires the HHA to make the discharge summary (already required under the existing conditions of participation) available to the patient's attending physician upon request. Also, as stated above, we are not requiring that the discharge summary be a separate piece of paper that is not part of the routine summary reports already being submitted to the physician.

Comment: One commenter requested that we specify the required contents of the discharge summary.

Response: We are specifically requiring only that the discharge summary include the patient's medical and health status at discharge. We are otherwise providing the HHAs the flexibility to include whatever additional information they consider to be relevant and necessary.

Hospice Care

Covered Services (Sec. 418.202)

Comment: One commenter expressed concern that this section would increase a hospice's operating costs because the commenter believed it would require that homemaker services be furnished by home health aides.

Response: The commenter misinterpreted the requirements of the paragraph. Although a home health aide can furnish homemaker services, Medicare does not require homemaker services furnished under the Medicare hospice benefit to be provided by home health aides. This section specifically distinguishes between home health aide services, which must be provided by an individual who meets the home health aide training and competency evaluation requirements of Sec. 484.36, and homemaker services, which can be provided by individuals who are not required to have completed any specific training or competency evaluation.

Changes From the Proposed Rule Made by This Final Rule

Following is a summary listing of provisions in this final rule that differ from those in the proposed rule. Additional minor clarifying or editorial changes have also been made.

We have revised proposed Sec. 409.43(b) to clarify the required content of physician orders.

We have revised proposed Sec. 409.43(c) to correct a printing error in the physician signature requirements.

We have revised proposed Sec. 409.43(d) to require the registered nurse or therapist who is responsible for furnishing or supervising the ordered services to sign verbal orders received by the HHA.

We have revised proposed Sec. 409.44 to include general requirements for coverage determinations.

We have revised proposed Sec. 409.42, Sec. 409.44, and Sec. 409.45 to replace the term ``speech therapist'' with ``speech-language pathologist'' and the term ``speech therapy'' with ``speech-language pathology services.''

We have revised proposed Sec. 409.45(a) to clarify that no dependent services may be covered after the final qualifying service has been furnished.

We have revised proposed Sec. 409.45(c)(2) to allow the provision of medical social services on a short-term basis to a beneficiary's family member or caregiver.

We have revised proposed Sec. 409.45(g)(1) to replace ``Council on Medical Education of the American Medical Association'' with ``Accreditation Council for Graduate Medical Education.''

We have revised proposed Sec. 409.47(b) to include the allowable home health outpatient settings specified in the Act.

We have added Sec. 409.49(c), which excludes Medicare home health coverage of services that would not be covered as inpatient services. This was inadvertently omitted from the proposed rule.

We have revised proposed Sec. 409.49(g) to exclude Medicare home health coverage of medical social services provided to family members except as provided in Sec. 409.45(c)(2).

We have revised Sec. 484.36(b)(2)(iii) to require a home health aide to receive at least 12 hours of in-service training during each 12-month period.

We are not including the proposed home health aide supervision requirements that had been located in proposed Secs. 484.36(d)(2) (i) and (ii).

We have revised the introductory paragraph of proposed Sec. 484.48 to require the HHA to inform the attending physician of the availability of the discharge summary and to send it to him or her upon request.

We have added a new Sec. 413.125 to refer to the rules on allowability of certain costs in Secs. 409.49(b) and 409.46.

Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all HHAs are considered to be small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

The provisions in this final rule clarify existing policy and represent minor changes to the proposed rule published September 27, 1991 (56 FR 49154). We have revised Sec. 409.45(a) to clarify that we do not cover dependent services after the final qualifying service has been furnished except under certain circumstances. Though we are not able to estimate the magnitude, we believe this change will result in Medicare program savings.

We have revised Sec. 409.45(c)(2) to allow provision of medical social services on a short-term basis to a beneficiary's family member or caregiver if it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the treatment of the beneficiary's medical condition or to his or her rate of recovery. Though this change could increase program expenditures, we believe the additional cost will be negligible because of the low volume of these services and offsetting savings if the beneficiary's rate of recovery is improved.

Several changes made to the proposed rule will benefit HHAs' administration and utilization of home health aides. We have revised Sec. 484.36(b)(2)(iii) to allow a home health aide to receive the required 12 hours of in-service training during a 12-month period instead of each calendar year. This change allows HHAs some flexibility in scheduling training.

Many commenters opposed the requirements of proposed Sec. 484.36(d)(2)(i) and (ii). We agreed and are deleting those sections from the final rule. Therefore, we are not mandating supervisory visits once a month while the home health aide is providing patient care, or mandating supervisory visits while the aide is furnishing services in all instances if the home health aide services are provided by an individual not employed directly by the HHA. These changes allow HHAs additional flexibility.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act since we have determined, and the Secretary certifies, that this final rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Collection of Information Requirements

Sections 409.43, 484.18, 484.36, and 484.48 of this document contain information collection requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504), we have submitted a copy of this document to OMB for its review of these information collection requirements.

However, these information collection requirements have been previously approved under the information collection requirements

contained in the conditions of participation for home health agencies. These information collection requirements implement patient rights provisions and set forth home health aide criteria; they were approved under the OMB approval number 0938-0365 on June 24, 1991 through December 31, 1993 by OMB in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). We are requesting reapproval of the collection requirements in those sections. Public reporting burden for these collections of information is estimated to be six hours per home health agency per year.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the ``ADDRESSES'' section of this preamble.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as follows:

A. Part 409 is amended as set forth below:

PART 409--HOSPITAL INSURANCE BENEFITS

1. The authority citation is revised to read as follows:

Authority: Secs. 1102, 1812, 1813, 1814, 1835, 1861, 1862 (a), (f), and (h), 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395d, 1395e, 1395f, 1395n, 1395x, 1395y(a), (f), and (h), 1395hh and 1395qq).

2. Section 409.32(a) is revised to read as follows:

Sec. 409.32 Criteria for skilled services and the need for skilled services.

(a) To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel.

* * * * *

3. Section 409.40 is revised to read as follows:

Sec. 409.40 Basis, purpose, and scope.

This subpart implements sections 1814(a)(2)(C), 1835(a)(2)(A), and 1861(m) of the Act with respect to the requirements that must be met for Medicare payment to be made for home health services furnished to eligible beneficiaries.

4. Section 409.41 is revised to read as follows:

Sec. 409.41 Requirement for payment.

In order for home health services to qualify for payment under the Medicare program the following requirements must be met:

(a) The services must be furnished to an eligible beneficiary by, or under arrangements with, an HHA that--

(1) Meets the conditions of participation for HHAs at part 484 of this chapter; and

(2) Has in effect a Medicare provider agreement as described in part 489, subparts A, B, C, D, and E of this chapter.

(b) The physician certification and recertification requirements for home health services described in Sec. 424.22.

(c) All requirements contained in Secs. 409.42 through 409.47.

5. Section 409.42 is revised to read as follows:

Sec. 409.42 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

(a) Confined to the home. The beneficiary must be confined to the home or in an institution that is not a hospital, SNF or nursing facility as defined in section 1861(e)(1), 1819(a)(1) or 1919(a)(1) of the Act, respectively.

(b) Under the care of a physician. The beneficiary must be under the care of a physician who establishes the plan of care. A doctor of podiatric medicine may establish a plan of care only if that is consistent with the HHA's policy and with the functions he or she is authorized to perform under State law.

(c) In need of skilled services. The beneficiary must need at least one of the following skilled services as certified by a physician in accordance with the physician certification and recertification requirements for home health services under Sec. 424.22 of this chapter.

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in Sec. 409.32. (Also see Sec. 409.33 (a) and (b) for a description of examples of skilled nursing and rehabilitation services.)

(2) Physical therapy services that meet the requirements of Sec. 409.44(b).

(3) Speech-language pathology services that meet the requirements of Sec. 409.44(b).

(4) Continuing occupational therapy services that meet the requirements of Sec. 409.44(b) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period.

(d) Under a plan of care. The beneficiary must be under a plan of care that meets the requirements for plans of care specified in Sec. 409.43.

(e) By whom the services must be furnished. The home health services must be furnished by, or under arrangements made by, a participating HHA.

6. Section 409.43 is revised to read as follows:

Sec. 409.43 Plan of care requirements.

(a) Contents. The plan of care must contain those items listed in Sec. 484.18(a) of this chapter that specify the standards relating to a plan of care that an HHA must meet in order to participate in the Medicare program.

(b) Physician's orders. The physician's orders for services in the plan of care must specify the medical treatments to be furnished as well as the type of home health discipline that will furnish the ordered services and at what frequency the services will be furnished. Orders for services to be provided ``as needed'' or ``PRN'' must be accompanied by a description of the beneficiary's medical signs and symptoms that would occasion the visit and a specific limit on the number of those visits to be made under the order before an additional physician order would have to be obtained. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished. If a range of visits is ordered, the upper limit of the range is considered the specific frequency.

(c) Physician signature. The plan of care must be signed and dated by a physician who meets the certification and recertification requirements of Sec. 424.22 of this chapter. The plan of care must be signed by the physician before the bill for services is submitted. Any changes in the plan must be signed and dated by the physician.

(d) Oral (verbal) orders. If any services are provided based on a physician's oral orders, the orders must be put in writing and be signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in Sec. 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Oral orders may only be accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The oral orders must also be countersigned and dated by the physician before the HHA bills for the care.

(e) Frequency of review. The plan of care must be reviewed by the physician (as specified in Sec. 409.42(b)) in consultation with agency professional personnel at least every 62 days. Each review of a beneficiary's plan of care must contain the signature of the physician who reviewed it and the date of review.

(f) Termination of the plan of care. The plan of care is considered to be terminated if the beneficiary does not receive at least one covered skilled nursing, physical therapy, speech-language pathology services, or occupational therapy visit in a 62-day period unless the physician documents that the interval without such care is appropriate to the treatment of the beneficiary's illness or injury.

7. Section 409.44 is revised to read as follows:

Sec. 409.44 Skilled services requirements.

(a) General. The intermediary's decision on whether care is reasonable and necessary is based on information provided on the forms and in the medical record concerning the unique medical condition of the individual beneficiary. A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care.

(b) Skilled nursing care. (1) Skilled nursing care consists of

those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in Sec. 484.4 of this chapter, and meet the criteria for skilled nursing services specified in Sec. 409.32. See Sec. 409.33 (a) and (b) for a description of skilled nursing services and examples of them.

(i) In determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice.

(ii) If the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service.

(iii) The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse.

(iv) If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

(2) The skilled nursing care must be provided on a part-time or intermittent basis.

(3) The skilled nursing services must be reasonable and necessary for the treatment of the illness or injury.

(i) To be considered reasonable and necessary, the services must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice.

(ii) The skilled nursing care provided to the beneficiary must be reasonable within the context of the beneficiary's condition.

(iii) The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.

(c) Physical therapy, speech-language pathology services, and occupational therapy. To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) through (4) of this section. Occupational therapy services initially qualify for home health coverage only if they are part of a plan of care that also includes intermittent skilled nursing care, physical therapy, or speech-language pathology services as follows:

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

(i) The services must be considered under accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy

assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in Sec. 484.4 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist .

(iii) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition, or the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program. If the services are for the establishment of a maintenance program, they may include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary infrequent reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical therapist, speech-language pathologist, or occupational therapist is required.

(iv) The amount, frequency, and duration of the services must be reasonable.

8. A new Sec. 409.45 is added to read as follows:

Sec. 409.45 Dependent services requirements.

(a) General. Services discussed in paragraphs (b) through (g) of this section may be covered only if the beneficiary needs skilled nursing care on an intermittent basis, as described in Sec. 409.44(a); physical therapy or speech-language pathology services as described in Sec. 409.44(b); or has a continuing need for occupational therapy services as described in Sec. 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period; and otherwise meets the qualifying criteria (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care) specified in Sec. 409.42. Home health coverage is not available for services furnished to a beneficiary who is no longer in need of one of the qualifying skilled services specified in this paragraph. Therefore, dependent services furnished after the final qualifying skilled service are not covered, except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

(b) Home health aide services. To be covered, home health aide services must meet each of the following requirements:

(1) The reason for the visits by the home health aide must be to provide hands-on personal care to the beneficiary or services that are needed to maintain the beneficiary's health or to facilitate treatment of the beneficiary's illness or injury. The physician's order must indicate the frequency of the home health aide services required by the beneficiary. These services may include but are not limited to:

(i) Personal care services such as bathing, dressing, grooming, caring for hair, nail and oral hygiene that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the beneficiary's condition, routine catheter care, and routine colostomy care), assistance with ambulation, changing position in bed, and assistance with transfers.

(ii) Simple dressing changes that do not require the skills of a licensed nurse.

(iii) Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively.

(iv) Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely and effectively performed, such as routine maintenance exercises and repetitive practice of functional communication skills to support speech-language pathology services.

(v) Routine care of prosthetic and orthotic devices.

(2) The services to be provided by the home health aide must be--

(i) Ordered by a physician in the plan of care; and

(ii) Provided by the home health aide on a part-time or intermittent basis.

(3) The services provided by the home health aide must be reasonable and necessary. To be considered reasonable and necessary, the services must--

(i) Meet the requirement for home health aide services in paragraph (b)(1) of this section;

(ii) Be of a type the beneficiary cannot perform for himself or herself; and

(iii) Be of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual.

(4) The home health aide also may perform services incidental to a visit that was for the provision of care as described in paragraphs (b)(3)(i) through (iii) of this section. For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal.

(c) Medical social services. Medical social services may be covered if the following requirements are met:

(1) The services are ordered by a physician and included in the plan of care.

(2)(i) The services are necessary to resolve social or emotional problems that are expected to be an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(ii) If these services are furnished to a beneficiary's family member or caregiver, they are furnished on a short-term basis and it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(3) The frequency and nature of the medical social services are reasonable and necessary to the treatment of the beneficiary's condition.

(4) The medical social services are furnished by a qualified social worker or qualified social work assistant under the supervision of a social worker as defined in Sec. 484.4 of this chapter.

(5) The services needed to resolve the problems that are impeding the beneficiary's recovery require the skills of a social worker or a

social work assistant under the supervision of a social worker to be performed safely and effectively.

(d) Occupational therapy. Occupational therapy services that are not qualifying services under Sec. 409.44(c) are nevertheless covered as dependent services if the requirements of Sec. 409.44(c)(2)(i) through (iv), as to reasonableness and necessity, are met.

(e) Durable medical equipment. Durable medical equipment in accordance with Sec. 410.38 of this chapter, which describes the scope and conditions of payment for durable medical equipment under Part B, may be covered under the home health benefit as either a Part A or Part B service. Durable medical equipment furnished by an HHA as a home health service is always covered by Part A if the beneficiary is entitled to Part A.

(f) Medical supplies. Medical supplies (including catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care but excluding drugs and biologicals) may be covered as a home health benefit. For medical supplies to be covered as a Medicare home health benefit, the medical supplies must be needed to treat the beneficiary's illness or injury that occasioned the home health care.

(g) Intern and resident services. The medical services of interns and residents in training under an approved hospital teaching program are covered if the services are ordered by the physician who is responsible for the plan of care and the HHA is affiliated with or under the common control of the hospital furnishing the medical services.

Approved means--

(1) Approved by the Accreditation Council for Graduate Medical Education;

(2) In the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;

(3) In the case of an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association; or

(4) In the case of an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatry Education of the American Podiatric Association.

Sec. 409.46 Coinsurance for durable medical equipment (DME) furnished as a home health service [Redesignated as Sec. 409.50]

9. Section 409.46 is redesignated as Sec. 409.50.

10. New Secs. 409.46 through 409.49 are added to read as follows:

Sec. 409.46 Allowable administrative costs.

Services that are allowable as administrative costs but are not separately billable include, but are not limited to, the following:

(a) Registered nurse initial evaluation visits. Initial evaluation visits by a registered nurse for the purpose of assessing a beneficiary's health needs, determining if the agency can meet those health needs, and formulating a plan of care for the beneficiary are allowable administrative costs. If a physician specifically orders that a particular skilled service be furnished during the evaluation in which the agency accepts the beneficiary for treatment and all other coverage criteria are met, the visit is billable as a skilled nursing visit. Otherwise it is considered to be an administrative cost.

(b) Visits by registered nurses or qualified professionals for the supervision of home health aides. Visits by registered nurses or

qualified professionals for the purpose of supervising home health aides as required at Sec. 484.36(d) of this chapter are allowable administrative costs. Only if the registered nurse or qualified professional visits the beneficiary for the purpose of furnishing care that meets the coverage criteria at Sec. 409.44, and the supervisory visit occurs simultaneously with the provision of covered care, is the visit billable as a skilled nursing or therapist's visit.

(c) Respiratory care services. If a respiratory therapist is used to furnish overall training or consultative advice to an HHA's staff and incidentally provides respiratory therapy services to beneficiaries in their homes, the costs of the respiratory therapist's services are allowable as administrative costs. Visits by a respiratory therapist to a beneficiary's home are not separately billable. However, respiratory therapy services that are furnished as part of a plan of care by a skilled nurse or physical therapist and that constitute skilled care may be separately billed as skilled visits.

(d) Dietary and nutrition personnel. If dieticians or nutritionists are used to provide overall training or consultative advice to HHA staff and incidentally provide dietetic or nutritional services to beneficiaries in their homes, the costs of these professional services are allowable as administrative costs. Visits by a dietician or nutritionist to a beneficiary's home are not separately billable.

Sec. 409.47 Place of service requirements.

To be covered, home health services must be furnished in either the beneficiary's home or an outpatient setting as defined in this section.

(a) Beneficiary's home. A beneficiary's home is any place in which a beneficiary resides that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1), of 1919(a)(1) of the Act, respectively.

(b) Outpatient setting. For purposes of coverage of home health services, an outpatient setting may include a hospital, SNF or a rehabilitation center with which the HHA has an arrangement in accordance with the requirements of Sec. 484.14(h) of this chapter and that is used by the HHA to provide services that either--

(1) Require equipment that cannot be made available at the beneficiary's home; or

(2) Are furnished while the beneficiary is at the facility to receive services requiring equipment described in paragraph (b)(1) of this section.

Sec. 409.48 Visits.

(a) Number of allowable visits under Part A. To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part A for an unlimited number of covered home health visits. All Medicare home health services are covered under hospital insurance unless there is no Part A entitlement.

(b) Number of visits under Part B. To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part B for an unlimited number of covered home health visits. Medicare home health services are covered under Part B only when the beneficiary is not entitled to coverage under Part A.

(c) Definition of visit. A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service.

(1) Generally, one visit may be covered each time an HHA employee or someone providing home health services under arrangements enters the beneficiary's home and provides a covered service to a beneficiary who meets the criteria of Sec. 409.42 (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care).

(2) If the HHA furnishes services in an outpatient facility under arrangements with the facility, one visit may be covered for each type of service provided.

(3) If two individuals are needed to provide a service, two visits may be covered. If two individuals are present, but only one is needed to provide the care, only one visit may be covered.

(4) A visit is initiated with the delivery of covered home health services and ends at the conclusion of delivery of covered home health services. In those circumstances in which all reasonable and necessary home health services cannot be provided in the course of a single visit, HHA staff or others providing services under arrangements with the HHA may remain at the beneficiary's residence between visits (for example, to provide non-covered services). However, if all covered services could be provided in the course of one visit, only one visit may be covered.

Sec. 409.49 Excluded services.

(a) Drugs and biologicals. Drugs and biologicals are excluded from payment under the Medicare home health benefit.

(1) A drug is any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other condition or for the relief of pain or suffering or to control or improve any physiological pathologic condition.

(2) A biological is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.

(b) Transportation. The transportation of beneficiaries, whether to receive covered care or for other purposes, is excluded from home health coverage. Costs of transportation of equipment, materials, supplies, or staff may be allowable as administrative costs, but no separate payment is made for them.

(c) Services that would not be covered as inpatient services. Services that would not be covered if furnished as inpatient hospital services are excluded from home health coverage.

(d) Housekeeping services. Services whose sole purpose is to enable the beneficiary to continue residing in his or her home (for example, cooking, shopping, Meals on Wheels, cleaning, laundry) are excluded from home health coverage.

(e) Services covered under the End Stage Renal Disease (ESRD) program. Services that are covered under the ESRD program and are contained in the composite rate reimbursement methodology, including any service furnished to a Medicare ESRD beneficiary that is directly related to that individual's dialysis, are excluded from coverage under the Medicare home health benefit.

(f) Prosthetic devices. Items that meet the requirements of Sec. 410.36(b) of this chapter for prosthetic devices covered under Part B are excluded from home health coverage. Catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care are not considered prosthetic devices if furnished under a home health plan of care and are not subject to this exclusion from coverage.

(g) Medical social services provided to family members. Except as provided in Sec. 409.45(c)(2), medical social services provided solely to members of the beneficiary's family and that are not incidental to

covered medical social services being provided to the beneficiary are not covered.

B. Part 413 is amended as set forth below:

PART 413--PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1814(b), 1815, 1833 (a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395g, 1395l (a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); sec. 104 of Public Law 100-360 as amended by sec. 608(d)(3) of Public Law 100-485 (42 U.S.C. 1395ww (note)); and sec. 101(c) of Public Law 101-234 (42 U.S.C. 1395ww (note)).

2. Section 413.125 is added to subpart F to read as follows:

Sec. 413.125 Payment for home health services.

For additional rules on the allowability of certain costs incurred by home health agencies, see Secs. 409.46 and 409.49(b) of this chapter.

C. Part 418 is amended as set forth below:

PART 418--HOSPICE CARE

1. The authority citation for part 418 is revised to read as follows:

Authority: Secs. 1102, 1812(a)(4), 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), 1816(e)(5), 1861(dd), 1862(a) (1), (6) and (9) and 1871 of the Social Security Act (42 U.S.C. 1302, 1395d(a)(4), 1395d(d), 1395e(a)(4), 1395f(a)(7), 1396f(i), 1395h(e)(5), 1395x(dd), 1395y(a) (1), (6) and (9) and 1395hh) and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 418.202 is amended by revising paragraph (g) to read as follows:

Sec. 418.202 Covered services.

* * * * *

(g) Home health aide services furnished by qualified aides as designated in Sec. 418.94 and homemaker services. Home health aides may provide personal care services as defined in Sec. 409.45(b) of this chapter. Aides may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing bed linens or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

* * * * *

D. Part 484 is amended as set forth below:

PART 484--CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

1. The authority citation for part 484 is revised to read as follows:

Authority: Secs. 1102, 1814(a)(2)(C), 1835(a)(2)(A), 1861, 1871, and 1891 of the Social Security Act (42 U.S.C. 1302, 1395f(a)(2)(C), 1395n(a)(2)(A), 1395x, 1395hh, and 1395bbb).

2. Section 484.18(c) is revised to read as follows:

Sec. 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

* * * * *

(c) Standard: Conformance with physician orders. Drugs and treatments are administered by agency staff only as ordered by the physician. Oral orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in Sec. 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Oral orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. Agency staff check all medicines a patient may be taking to identify possible ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindicated medication, and promptly report any problem to the physician.

3. In Sec. 484.36, paragraphs (b)(2)(iii), (c) and (d) are revised to read as follows:

Sec. 484.36 Condition of participation: Home health aide services.

* * * * *

(b) * * *

(2) * * *

(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.

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(c) Standard: Assignment and duties of the home health aide.

(1) Assignment. The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

(2) Duties. The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered. Any home health aide services offered by an HHA must be provided by a qualified home health aide.

(d) Standard: Supervision.

(1) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy,

occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

(2) The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an on-site visit to the patient's home no less frequently than every 2 weeks.

(3) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 62 days. In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

(4) If home health aide services are provided by an individual who is not employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act. If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA's (or hospice's) responsibilities include, but are not limited to-- (i) Ensuring the overall quality of the care provided by the aide;

(ii) Supervision of the aide's services as described in paragraphs (d)(1) and (d)(2) of this section; and

(iii) Ensuring that home health aides providing services under arrangements have met the training requirements of paragraph (a) of this section.

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5. In Sec. 484.48, the introductory paragraph is revised to read as follows:

Sec. 484.48 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

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(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: May 31, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: June 24, 1994.

Donna E. Shalala,

Secretary.

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