

Medicare Home Health Agency Manual

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NEW/REVISED MATERIAL--EFFECTIVE DATE: January 22, 2002

As required by law, CMS implemented the home health prospective payment system (PPS) on October 1, 2000. In the revised sections, CMS has provided clarification to current policy governing Medicare home health PPS. In addition, CMS has provided clarification of the statutory changes to eligibility and coverage as required by the Balanced Budget Act (BBA) of 1997 and the Beneficiary Improvement and Protection Act (BIPA) of 2000. Many of the policies have been previously issued in CMS program memoranda.

Section 200, Home Health Agency, incorporates language from the law governing consolidated billing requirements for home health agencies (HHAs) under the home health prospective payment system (PPS).

Section 200.2, Arrangements by Home Health Agencies, includes language that the agency must ensure arranged-for services comply with the home health conditions of participation.

Section 201, Home Health Prospective Payment System, creates new sections in the manual to provide specific clarification to home health PPS policies.

Section 201.1, National 60 Day Episode Rate, describes the policy governing the 60 day episode rate under home health PPS.

Section 201.2, Adjustments to the 60 Day Episode Rates, includes the policy for the case mix and wage index adjustment of the PPS rates.

Section 201.3, Continuous 60 Day Episode Recertification, describes the continuous episode recertification policy for patients who continue to be eligible for the Medicare home health benefit.

Section 201.4, Counting 60 Day Episodes, incorporates the policy for counting billable visit dates for both initial and subsequent episodes.

Section 201.5, Split Percentage Payment Approach to the 60 Day Episode, incorporates the policy for the split percentage payment of initial and subsequent episodes.

Section 201.6, Physician Signature Requirements for the Split Percentage Payments, describes the policy governing physician signature requirements for initial and final percentage payments.

Section 201.7, Low Utilization Payment Adjustment, includes the policy for episodes with four or fewer visits.

Section 201.8, Partial Episode Payment Adjustment, describes the policy for episodes in which a beneficiary elects to transfer and/or the beneficiary is discharged and returns to the same home health agency within the same 60 day episode.

Section 201.9, Significant Change in Condition Payment Adjustment (SCIC), incorporates the criteria and payment policy for patients who experience a significant change in condition during a 60 day episode.

Section 201.10, Outlier Payments, includes the policy for outlier payments under home health PPS.

Section 201.11, Discharge Issues, describes the policies governing hospice election mid-episode, patient's death, patients who are no longer eligible for Medicare home health, a patient discharge due to patient refusal of services or is a documented safety threat, abuse threat or is non-compliant, a patient who becomes managed care eligible mid episode, an intervening hospital or skilled nursing facility stay, submission of the final claims prior to the end of the 60 day episode, patient discharge and financial responsibility for Part B bundled medical supplies and services, and discharge issues associated with an inpatient admission overlapping into subsequent episodes.

Section 201.12, Consolidated Billing, incorporates the policy for the consolidated billing requirements governing home health PPS.

Section 201.13, Telehealth, includes the policies governing the adoption of telehealth technologies in the Medicare home health setting.

Section 201.14, Change of Ownership Relationship to Episodes Under PPS, incorporates the policies for change of ownership with assignment, change of ownership without assignment, and change of ownership-mergers.

Section 203.1, Reasonable and Necessary Services, is revised to include the Outcomes and Assessment Information Set (OASIS) as a subset of supplementary forms to the home health plan of care.

Section 204.1, Confined to the Home, includes language that reflects §507 of the BIPA of 2000 clarification to the definition of homebound for purposes of Medicare home health eligibility. New language is added to clarify homebound in terms of patients who reside at assisted living facilities, group homes & personal care homes, patients who attend adult day care programs, the state licensure/certification of day care facilities, and the determination of the therapeutic, medical or psychosocial treatment of the patient at the day care facility.

Section 204.2, Services Are Provided Under a Plan of Care Established and Approved by a Physician, is revised to reflect a 60 day episode under PPS; provides clarification of the timeliness of signature requirements for the initial percentage payment and the final percentage payment under home health PPS; replaces current venipuncture examples with IV medication administration examples in order to conform with BBA 1997 change that excluded venipuncture as sole reason for Medicare home health eligibility and revises current language to reflect a 60 day episode under PPS; clarifies that an HHA must have safeguards to prevent unauthorized access to the records and a process for reconstruction of the records in the event of a system breakdown or upon request from the intermediary, state surveyor, or other authorized personnel; and adds the policy governing sequencing of services ordered in the home health plan of care.

Section 204.4, Needs Skilled Nursing Care on an Intermittent Basis (Other than Solely Venipuncture for the Purposes of Obtaining a Blood Sample) or Physical Therapy or Speech-Language Pathology Services or Has Continued Need for Occupational Therapy, incorporates language from BBA 1997 reflecting the statutory change that eliminated venipuncture for the purpose of obtaining a blood sample as the sole reason for eligibility for the Medicare home health benefit.

Section 204.5, Physician Certification, incorporates language from BBA 1997 reflecting the statutory change that eliminated venipuncture for the purpose of obtaining a blood sample as the sole reason for eligibility for the Medicare home health benefit.

Section 205.1, Skilled Nursing Care, is reworded to be consistent with the BBA 1997 statutory change that eliminated venipuncture for the purpose of obtaining a blood sample as the sole reason for eligibility for the Medicare home health benefit.

Section 205.2, Skilled Therapy Services, is added to provide clarification of the scope of coverage of wound care services provided by qualified physical therapists under the Medicare home health benefit. This section also addresses the relationship between wound care provided by qualified physical therapists and the case mix methodology under home health PPS.

Section 206.2, Home Health Aide Services, is revised to incorporate the policy governing the delegation of insulin administration by home health aides within the scope of state practice acts.

Section 206.4, Medical Supplies (Except for Drugs and Biologicals) and the Use of Durable Medical Equipment, makes clarifying revisions to the existing section to address several issues regarding the bundling of medical supplies into the PPS rates and the consolidated billing responsibilities for medical supplies under home health PPS.

Section 206.7, Part-time or Intermittent Home Health Aide and Skilled Nursing Services, incorporates the BBA 1997 statutory clarification of the coverage of part-time or intermittent skilled nursing services and part-time or intermittent home health aide services under the Medicare home health benefit.

Section 212, Special Conditions for Coverage and Payment of Home Health Services Under Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B), replaces existing language with the BBA 1997 Part A and Part B financing shift revisions.

Section 212.1, Post-Institutional Home Health Services Furnished During a Home Health Spell-of-Illness Insurance (Part A) and Supplementary Medical Insurance (Part B),

Section 212.2, Beneficiaries Enrolled in Parts A and B Meet the Institutional Care Threshold, incorporates the policy governing the institutional care threshold required for Part A financing of Medicare home health for beneficiaries who are enrolled in both Parts A and B.

Section 212.3, Beneficiaries Who Are Enrolled in Part A and Part B, but do Not Meet the Threshold for Post-Institutional Home Health Services, provides the policy for Part B financing of the Medicare home health benefit for eligible beneficiaries who are enrolled in Parts A and B, but do not meet the threshold for post-institutional home health services.

Section 212.4, Beneficiaries Who Are Part A Only or Part B Only, includes the policy for the financing of Medicare home health services for beneficiaries who are enrolled in Part A only or Part B only.

Section 212.5, Coinsurance, Copayments, and Deductibles, provides clarification that the Part A and Part B financing shift, as required by BBA 1997, did not change the treatment of coinsurance, copayments and deductibles for Medicare home health services.

Section 215.1, Number of Home Health Visits Under Hospital Insurance (Part A), is reworded to reflect the BBA 1997 Part A and Part B financing shift implications.

Section 215.2, Number of Home Health Visits Under Supplementary Medical Insurance (Part B), incorporates the BBA 1997 Part A and Part B financing shift changes.

Section 218.2, Counting Visits, provides clarification to existing examples.

Section 218.3, Evaluation Visits, is reworded to reflect the 60 day episode under home health PPS.

Section 219, Medical and Other Health Services, is revised to reflect the consolidated billing requirements governing patients under a home health plan of care under home health PPS.

Section 219.1, Surgical Dressings, and Other Dressings Used for Reduction of Fractures and Dislocations, provides additional clarifying language on the policies governing consolidated billing under home health PPS.

Section 219.2, Prosthetic Devices, incorporates additional clarifying language on the policies governing consolidated billing under home health PPS.

Section 219.4, Outpatient Physical Therapy, Occupational Therapy, and Speech Pathology Services, provides additional clarifying language on the policies governing consolidated billing under home health PPS.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

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200. HOME HEALTH AGENCY

A home health agency (HHA) is a public agency or private organization, or a subdivision of such an agency or organization, that meets the following requirements:

A. It is primarily engaged in providing skilled nursing services and other therapeutic services, such as physical therapy, speech-language pathology services, or occupational therapy, medical social services, and home health aide services.

1. The law governing the Medicare home health prospective payment system (PPS) requires that all payments be made to the home health agency for any services and medical supplies (as described in §1861(m)(5) of the Social Security Act (the Act except for durable medical equipment (DME)) that are furnished to an individual during the time the individual is under a home health plan of care. This applies without regard to whether or not the item or service was furnished by the agency, by others under contract or arrangement with the agency, or otherwise.

2. Under the consolidated billing requirement governing home health PPS, we require that the HHA submit all Medicare claims for all home health services included in §1861(m) of the Act, but excluding DME while the eligible beneficiary is under a home health plan of care (see §201 for consolidated billing details). HHAs may provide the covered home health services (except DME) either directly or under arrangement.

3. An HHA must furnish at least one of the qualifying services directly through agency employees on a visiting basis in a place of residence used as a patient's home, but may furnish the second qualifying service and additional services under arrangement with another HHA or organization.

B. It has policies established by a professional group associated with the agency or organization (including at least one physician and one registered nurse) to govern the services and provides for supervision of such services by a physician or a registered nurse.

C. It maintains clinical records on all patients.

D. It is licensed in accordance with State or local law or is approved by the State or local licensing agency as meeting the licensing standards, where applicable.

E. It meets other conditions found by the Secretary of Health and Human Services to be necessary for health and safety.

For services under hospital insurance, the term "home health agency" does not include any agency or organization that is primarily for the care and treatment of mental disease.

200.1 Subdivision of Agencies.--When the subdivision of an agency, such as the home care department of a hospital or the nursing division of a health department, wishes to participate as a home health agency, the subdivision must meet the conditions of participation and must maintain records in such a way that subdivision activities and expenditures attributable to services provided under the health insurance program are identifiable.

200.2 Arrangements by Home Health Agencies.--

A. A home health agency (HHA) may have others furnish covered items or services through arrangements under which receipt of payment by the HHA for the services discharges the liability of the patient or any other person to pay for the services. Whether the items and services are provided by the HHA itself or by another agency under arrangements, both must agree not to charge the patient for covered items and services and must also agree to return money incorrectly collected.

In permitting HHAs to furnish services under arrangements, it was not intended that the agency merely serve as a billing mechanism for the other party. Accordingly, for services provided under arrangements to be covered, the agency must exercise professional responsibility over the arranged-for services **and ensure compliance with the home health conditions of participation.**

The agency's professional supervision over arranged-for services requires application of many of the same quality controls as are applied to services furnished by salaried employees. The agency must accept the patient for treatment in accordance with its administration policies, maintain a complete and timely clinical record of the patient that includes diagnosis, medical history, physician's orders, and progress notes relating to all services received; maintain liaison with the attending physician with regard to the progress of the patient and to assure that the required plan of treatment is periodically reviewed by the physician; secure from the physician the required certifications and recertifications; and ensure that the medical necessity of such services is reviewed on a sample basis by the agency's staff or an outside review group.

There are 3 situations in which an HHA may have arrangements with another health organization or person to provide home health services to patients:

1. Where an agency or organization, in order to be approved to participate in the program, makes arrangements with another organization or individual to provide the nursing or other therapeutic services that it cannot provide directly.

2. Where an agency that is already approved for participation, makes arrangements with others to provide services it does not provide.

3. Where an agency that is already approved for participation, makes arrangements with a hospital, skilled nursing facility, or rehabilitation center for services on an outpatient basis because the services involve the use of equipment that cannot be made available to the patient in his/her place of residence.

B. If an agency's subdivision (acting in its capacity as an HHA) makes an arrangement with its parent agency for the provision of certain items or services, there need not be a contract or formal agreement. If, however, the arrangement is made between the HHA and another provider participating in the health insurance program (hospital, skilled nursing facility, or HHA, and, in the case of physical therapy, occupational therapy, or speech-language pathology services, clinics, rehabilitation agencies, and public health agencies), there must be a written statement regarding the services to be provided and the financial arrangements.

C. If the arrangements are with an agency or organization that is not a qualified provider of services, there must be a written contract that includes all of the following:

1. A description of the services to be provided.
2. The duration of the agreement and how frequently it is to be reviewed.
3. A description of how personnel will be supervised.
4. A statement that the contracting organization will provide services in accordance with the plan of care established by the patient's physician in conjunction with the HHA's staff.
5. A description of the contracting organization's standards for personnel, including qualifications, functions, supervision, and inservice training.

6. A description of the method of determining reasonable costs and reimbursement by the HHA for the specific services to be provided by the contracting organization.

7. An assurance that the contracting organization will comply with title VI of the Civil Rights Act.

D. If an HHA notifies a beneficiary of noncoverage of services that another party has been furnishing under arrangements entered into by the agency, the initial notice, in and of itself, does not negate the contract between the agency and the other party. Unless the evidence shows that the contract has been formally terminated, the beneficiary is still considered to be the agency's patient and the other party to be the representative of the agency. Consequently, if upon initial notice that a service is no longer covered the other party continues to provide services to the patient, the other party is considered to be furnishing the services under arrangements with the home health agency, absent evidence to the contrary. Thus, if a beneficiary appeals the noncoverage of any or all of the arranged for services furnished after the notice, and a ruling is made in favor of the beneficiary, those services ruled on favorably would be reimbursable since they would constitute services furnished under arrangements by a certified HHA. If the denial is sustained, however, the other party cannot bill the beneficiary for the denied services since the HHA, not the other party, is responsible for the care rendered.

200.3 Rehabilitation Centers.--When the services are of such a nature that they cannot be administered at the patient's residence and are administered at a rehabilitation center which is not participating in the program as a hospital, skilled nursing facility, or HHA, the rehabilitation center must meet certain standards. The physical plant and equipment of such a rehabilitation center must meet all applicable State and local legal requirements for construction, safety, health, and design, including safety, sanitation and fire regulations, building codes, and ordinances. Given the statutory definition, a community mental health center is not considered a rehabilitation center.

201. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM

The unit of payment under home health PPS is a national 60 day episode rate with applicable adjustments.{PRIVATE }

201.1 National 60 Day Episode Rate.--

A. Services Included.--The law requires the 60 day episode to include all covered home health services, including medical supplies, paid on a reasonable cost basis. That means the 60-day episode rate includes costs for the six home health disciplines and the costs for routine and non-routine medical supplies. The six home health disciplines included in the 60 day episode rate are: skilled nursing services, home health aide services, physical therapy, speech-language pathology services, occupational therapy services, and medical social services.

The 60 day episode rate also includes amounts for: non-routine medical supplies and therapies that could have been unbundled to part B prior to PPS, ongoing reporting costs associated with the outcome and assessment information set (OASIS), and a one time first year of PPS cost adjustment reflecting implementation costs associated with the revised OASIS assessment schedules needed to classify patients into appropriate case mix categories.

B. Excluded Services.--The law specifically excludes durable medical equipment from the 60 day episode rate and consolidated billing requirements. The DME continues to be paid on the fee schedule outside of the PPS rate. The osteoporosis drug is also excluded from the 60 day episode rate but must be billed by the home health agency while a patient is under a home health plan of care since the law requires consolidated billing of osteoporosis drugs. The osteoporosis drug continues to be paid on a reasonable cost basis.

201.2 Adjustments to the 60 Day Episode Rates.--

A. Case Mix Adjustment.--A case mix methodology adjusts payment rates based on characteristics of the patient and his/her corresponding resource needs (e.g., diagnosis, clinical factors, functional factors, service needs). The 60 day episode rates are adjusted by case mix methodology based on data elements from the OASIS. The data elements of the case mix adjustment methodology are organized into three dimensions to capture clinical severity factors, functional severity factors, and service utilization factors influencing case mix. In the clinical, functional and service utilization dimensions, each data element is assigned a score value. The scores are summed to determine the patient's case mix group.

B. Labor Adjustments.--The labor portion of the 60 day episode rates are adjusted to reflect the wage index based on the site of service of the beneficiary. The beneficiary's location is the determining factor for the labor adjustment. The home health PPS rates are adjusted by the pre-floor and pre-reclassified hospital wage index. The hospital wage index is adjusted to account for the geographic reclassification of hospitals in accordance with §§1886(d)(8)(B) and 1886(d)(10) of the Act. According to the law, geographic reclassification only applies to hospitals. Additionally, the hospital wage index has specific floors that are required by law. Because these reclassifications and floors do not apply to HHAs, the home health rates are adjusted by the pre-floor and pre-reclassified hospital wage index.

NOTE: The pre-floor and pre-reclassified hospital wage index varies slightly from the numbers published in the Medicare inpatient hospital PPS regulation that reflects the floor and reclassification adjustments. The wage indices published in the home health final rule and subsequent annual updates reflect the most recent available pre-floor and pre-reclassified hospital wage index available at the time of publication.

201.3 Continuous 60 Day Episode Recertification.--Home health PPS permits continuous episode recertifications for patients who continue to be eligible for the home health benefit. Medicare does not limit the number of continuous episode recertifications for beneficiaries who continue to be eligible for the home health benefit.

201.4 Counting 60-Day Episodes.--

A. Initial Episodes.--The "From" date for the initial certification must match the start of care (SOC) date which is the first billable visit date for the 60 day episode. The "To" date is up to and including the last day of the episode which is not the first day of the subsequent episode. The "To" date can be up to, but never exceed a total of 60 days that includes the SOC date plus 59 days.

B. Subsequent Episodes.--If a patient continues to be eligible for the home health benefit, the home health PPS permits continuous episode recertifications. At the end of the 60 day episode, a decision must be made whether or not to recertify the patient for a subsequent 60 day episode. An eligible beneficiary who qualifies for a subsequent 60 day episode would start the subsequent 60 day episode on day 61. The "From" date for the first subsequent episode is day 61 up to including day 120. The "To" date for the subsequent episode in this example can be up to, but never exceed a total of 60 days that includes day 61 plus 59 days.

201.5 Split Percentage Payment Approach to the 60 Day Episode.--In order to ensure adequate cash flow to HHAs, the home health PPS has set forth a split percentage payment approach to the 60 day episode. The split percentage occurs through the request for anticipated payment (RAP) at the start of the episode and the final claim at the end of the episode. For initial episodes, there will be a 60/40 split percentage payment. An initial percentage payment of 60 percent of the episode will be paid at the beginning of the episode and a final percentage payment of 40 percent will be paid at the end of the episode, unless there is an applicable adjustment. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes will be paid at a 50/50-percentage payment split.

201.6 Physician Signature Requirements for the Split Percentage Payments.--

A. Initial Percentage Payment.--If a physician signed plan of care is not available at the beginning of the episode, the HHA may submit a RAP for the initial percentage payment based on physician verbal orders OR a referral prescribing detailed orders for the services to be rendered that is signed and dated by the physician. If the RAP submission is based on physician verbal orders, the verbal order must be recorded in the plan of care, include a description of the patient's condition and the services to be provided by the home health agency, include an attestation (relating to the physician's orders and the date received per 42 CFR 409.43), and the plan of care is copied and immediately submitted to the physician. A billable visit must be rendered prior to the submission of a RAP.

CMS has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders and is not a Medicare claim for purposes of the Act (although it is a claim for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law, Civil False Claims Act and the Criminal False Claims Act), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.

B. Final Percentage Payment.--The plan of care must be signed and dated by a physician who meets the certification and recertification requirements of §424.22 before the claim for each episode for services is submitted for the final percentage payment. Any changes in the plan of care must be signed and dated by a physician.

201.7 Low Utilization Payment Adjustment.--An episode with four or fewer visits is paid the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary. Such episodes of four or fewer visits are paid the wage adjusted per visit amount for each of the visits rendered instead of the full episode amount. The national per visit amounts by discipline (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services) are updated annually by the applicable market basket for each visit type and published annually.

201.8 Partial Episode Payment Adjustment.--

A. Partial Episode Payment Adjustment Criteria.--The partial episode payment adjustment (PEP) accounts for key intervening events in a patient's care defined as:

- A beneficiary elected transfer, or
- A discharge resulting from the beneficiary reaching the treatment goals in the original plan of care and returning to the same HHA during the 60 day episode.

The intervening event defined as the beneficiary elected transfer or discharge and return to the same HHA during the 60 day episode warrants a new 60 day episode for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required. When a new 60 day episode begins due to the intervening event of the beneficiary elected transfer or discharge and return to the same HHA during the 60 day episode, the original 60 day episode is proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event.

B. Methodology Used To Calculate PEP Adjustment.--The PEP adjustment for the original 60 day episode is calculated to reflect the length of time the beneficiary remained under the care of the original HHA based on the first billable visit date through and including the last billable visit date. The PEP adjustment is calculated by determining the actual days served by the original HHA (first billable visit date through and including last billable visit date as a proportion of 60 multiplied by the original 60 day episode payment).

C. Application of Therapy Threshold to PEP Adjusted Episode.--The therapy threshold item included in the case mix methodology used in home health PPS is not combined or prorated across episodes. Each episode whether full or proportionately adjusted is subject to the therapy threshold for purposes of case mix adjusting the payment for that individual patient's resource needs.

D. Common Ownership Exception to PEP Adjustment.--If an HHA has a significant ownership as defined in §424.22, then the PEP adjustment would not apply in those situations of beneficiary elected transfer. Those situations would be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the ownership interest until the end of the episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moved out of their MSA or non-MSA during the 60 day episode before the transfer to the receiving HHA.

E. Beneficiary Elected Transfer Verification.--In order for a receiving HHA to accept a beneficiary elected transfer, the receiving HHA must document that the beneficiary has been informed that the initial HHA will no longer receive Medicare payment on behalf of the patient and will no longer provide Medicare covered services to the patient after the date of the patient's elected transfer in accordance with current patient rights requirements at 42 CFR 484.10(e). The receiving HHA must also document in the record that it accessed the regional home health intermediaries (RHHI) inquiry system to determine whether or not the patient was under an established home health plan of care and contacted the initial HHA on the effective date of transfer. In the rare circumstance of a dispute between HHAs, if the receiving HHA can provide documentation of its notice of patient rights on Medicare payment liability provided to the patient upon transfer and the contact of the initial HHA of the transfer date, then the initial HHA will be ineligible for payment in addition to the appropriate PEP adjustment. If the receiving HHA cannot provide the appropriate documentation, the receiving HHA's RAP and/or final claim will be cancelled and full episode payment will be provided to the initial HHA.

201.9 Significant Change in Condition Payment Adjustment (SCIC).--If a patient experiences a significant change in condition during a 60 day episode that was not envisioned in the original plan of care, the 60 day episode rate may be changed with a SCIC adjustment to reflect the payment level to meet the resource needs of the patient during the 60 day episode.

A. Significant Change in Condition Adjustment Criteria.--In order to receive a new case mix assignment due to an unanticipated significant change in condition, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in treatment approach in the patient's plan of care. The total significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both before and after the patient experienced a significant change in condition during the 60 day episode.

B. Methodology Used to Calculate the SCIC Adjustment.--The SCIC payment adjustment is calculated in two parts. The first part of the SCIC payment adjustment reflects the adjustment to the payment level prior to the patient's significant change in condition during the 60 day episode. The first part of the SCIC adjustment is determined by taking the span of days of the first billable visit date through and including the last billable visit date prior to the patient's significant change in condition as a proportion of 60 multiplied by the original episode amount. The second part of the SCIC payment adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60 day episode. The second part of the SCIC adjustment is calculated using the span of days of the first billable visit date through and including the last billable visit date through the balance of the 60 day episode. The agency is not constrained to bill for a SCIC for a higher HHRG if the net effect is a lower payment for the episode than if the SCIC had not occurred. Because the intent of the SCIC was not to lower the total episode payment when patients actually required more intensive services, the HHA is not forced to bill for a SCIC in this circumstance. However, where the SCIC reflects a lower HHRG due to unanticipated improvement in patient condition, the SCIC must be billed.

C. Application of Therapy Threshold to the SCIC and Relationship of Therapy Need Changes to the SCIC Adjustment.--The therapy threshold item included in the case mix methodology used in home health PPS is not combined or prorated across episodes. Since the SCIC adjustment occurs within a given 60 day episode, all therapy provided within a SCIC adjusted episode is counted toward the therapy threshold for the episode. The intermediary system will not automatically upgrade a non-therapy HHRG to a therapy HHRG when the final claim indicates 10 or more therapy visits even when 10 or more therapy visits are furnished and recorded on the claim. If the therapy threshold is the only case mix item that requires adjustment, the HHA may cancel and resubmit a RAP with the corrected HHRG that reflects the upwardly revised therapy level. However, if the patient's actual therapy receipt as reflected on the final claim is lower than the threshold for the high therapy case mix group projected at the initiation of the episode, the intermediary system will automatically lower the reimbursement level to the lower therapy case mix group.

D. Relationship Between SCIC Adjustments and the Low Utilization Payment Adjustment.--The SCIC adjustment occurs within a given 60 day episode and does not restart the 60 day episode clock. The LUPA adjustment applies to a total 60 day episode period. As long as the total SCIC adjusted episode, comprised of both the pre-SCIC and post-SCIC parts, has more than four visits, the total episode would not be considered a LUPA situation. The LUPA applies to the total number of visits provided in a given 60 day episode.

E. Intervening Hospital or SNF Stay SCIC Adjustment.--HHAs have the option to discharge the patient within the scope of their own operating policies; however, an HHA discharging a patient as a result of hospital (SNF or rehab facility) admission with the patient returning to home health services at the same HHA during the 60 day episode will not be recognized by Medicare as a discharge for billing and payment purposes. An intervening hospital (SNF or rehab facility) stay will result in either an applicable SCIC adjustment or, if the resumption of care OASIS assessment upon return to home health does not indicate a change in case-mix level, a full 60 day episode will be provided spanning the start of care date prior to the hospital (SNF or rehab facility) admission, through and including the days of the hospital admission, and ending 59 days after the original start of care date.

201.10 Outlier Payments.--When cases experience an unusually high level of services in a 60 day period, Medicare systems will provide additional or "outlier" payments to the case-mix and wage adjusted episode payment. Outlier payments can result from medically necessary high utilization in any or all-home health service disciplines. CMS makes outlier payments when the cost of care exceeds a threshold dollar amount. The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode or the total SCIC adjustment amount for the episode plus a fixed dollar loss amount is the same for all case-mix groups. The outlier payment is a proportion of the amount of imputed costs beyond the threshold. CMS calculates the imputed cost for each episode by multiplying the national per visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines. If the imputed cost for the episode is greater than the sum of the case mix and wage adjusted episode payment plus the fixed dollar loss amount (the outlier threshold), a set percentage (the loss sharing ratio) of the difference between the imputed amount and outlier threshold will be paid to the HHA as a wage adjusted outlier payment in addition to the episode payment. The amount of the outlier payment is determined as follows:

- Calculate the case-mix and wage adjusted episode payment;
- Add the wage adjusted fixed dollar loss amount. The sum of steps 1 & 2 is the outlier threshold for the episode;
- Multiply the wage adjusted national per visit rate for each home health discipline by the total number of visits for each home health discipline to determine the imputed cost of all visits. The result yields the total imputed costs for the episode;
- Subtract the total imputed costs for the episode (total from Step 3) from the sum of the case-mix and wage adjusted episode payment and the wage adjusted fixed dollar loss amount (sum of Steps 1& 2—outlier threshold);
- Multiply the difference by the loss sharing ratio; and
- The result of Step 5 is wage index adjusted. That total amount is the outlier payment for the episode.

201.11 Discharge Issues.--

A. Hospice Election Mid-Episode.--If a patient elects hospice before the end of the episode and there was no SCIC, PEP or LUPA adjustment, the HHA will receive a full episode payment. Home health PPS does not change the current rules that permit a hospice patient to receive home health services for a condition unrelated to his/her reason for hospice election. Consistent with all episodes in which a patient receives four or fewer visits, the episode with four or fewer visits in

which a patient elects hospice would be paid at the low utilization payment adjusted amount. In the event of a patient election of hospice during a SCIC adjusted episode, the total SCIC adjusted episode would constitute the full episode payment. However, the HHA is not constrained to bill for a SCIC for a higher case mix group if the net effect is a lower payment for the episode than if the SCIC had not occurred.

B. Patient Death's.--The documented event of a patient's death would result in a full episode payment, unless the death occurred in a low utilization payment adjusted episode. Consistent with all episodes in which a patient receives four or fewer visits, if the patient's death occurred during an episode with four or fewer visits, the episode would be paid at the low utilization payment adjusted amount. In the event of a patient's death during a SCIC adjusted episode, the total SCIC adjusted episode would constitute the full episode payment. However, the HHA is not constrained to bill for a SCIC for a higher case mix group if the net effect is a lower payment for the episode than if the SCIC had not occurred.

C. Patient is No Longer Eligible for Home Health (e.g., no longer homebound, no skilled need).--If the patient is discharged because he or she is no longer eligible for the Medicare home health benefit and has received more than four visits, then the HHA would receive full episode payment unless the patient becomes subsequently eligible for the Medicare home health benefit during the same 60 day episode and later transferred to another HHA or returned to the same HHA, then the latter situation would result in a PEP adjustment.

D. Discharge due to Patient Refusal of Services or is a Documented Safety Threat, Abuse Threat, or is Non-Compliant.--If the patient is discharged because he or she refuses services or becomes a documented safety, abuse or non-compliance discharge and has received more than four visits, then the HHA would receive full episode payment unless the patient becomes subsequently eligible for the Medicare home health benefit during the same 60 day episode and later transferred to another HHA or returned to the same HHA, then the latter situation would result in a PEP adjustment.

E. Patient Becomes Managed Care Eligible Mid Episode.--If a patient becomes HMO eligible mid episode, the 60 day episode payment will be proportionally adjusted with a PEP adjustment.

F. Intervening Hospital or SNF Stay SCIC Adjustment.--HHAs have the option to discharge the patient within the scope of their own operating policies; however, an HHA discharging a patient as a result of hospital (SNF or rehab facility) admission during the 60 day episode will not be recognized by Medicare as a discharge for billing and payment purposes. An intervening hospital (SNF or rehab facility) stay will result in either an applicable SCIC adjustment or, if the resumption of care OASIS assessment upon return to home health does not indicate a change in case-mix level, a full 60 day episode will be provided spanning the start of care date prior to the hospital (SNF or rehab facility) admission, through and including the days of the hospital admission, and ending 59 days after the original start of care date.

G. Submission of Final Claims Prior to the End of the 60 Day Episode.--The claim may be submitted upon discharge before the end of the 60 day episode. However, subsequent adjustments to any payments based on the claim may be made due to an intervening event resulting in a PEP adjustment or other adjustment.

H. Patient Discharge and Financial Responsibility for Part B Bundled Medical Supplies and Services.--As discussed in detail under §201.12, the law governing the Medicare home health PPS requires the HHA to provide all bundled home health services (except DME) either directly or under arrangement while a patient is under a home health plan of care during an open episode. The HHA is responsible for providing all covered home health services (except DME) and the bundled Part B medical supplies and therapy services that could have been previously unbundled prior to PPS either directly or under arrangement while a patient is under a home health plan of care during an open episode. Once the patient is discharged, the HHA is no longer responsible for providing home health services including the bundled Part B medical supplies and therapy services.

I. Discharge Issues Associated With Inpatient Admission Overlapping Into Subsequent Episodes.--If a patient is admitted to an inpatient facility and the inpatient stay overlaps into what would have been the subsequent episode and there is no reassessment or recertification of the patient, then the certification begins with the new start of care date after inpatient discharge.

201.12 Consolidated Billing.--The law governing the Medicare home health PPS effective October 1, 2000, requires that payment for home health services (including medical supplies described in §1861(m)(5) of the Social Security Act (the Act), but excluding DME to the extent provided for in such section) furnished to an individual who (at the time the item or service was furnished) is under a plan of care of a HHA, be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or under any other contracting or consulting arrangement, or otherwise). Under the consolidated billing requirement governing home health PPS, we require that the HHA submit all Medicare claims for all home health services included in §1861(m) of the Act, but excluding DME provided while the eligible beneficiary is under a plan of care. The HHAs must provide the covered home health services (except DME) either directly or under arrangement. Payment for all services and supplies, with the exception of the osteoporosis drugs and DME, are included in the PPS episodic rate.

A. Home Health Services Subject to Consolidated Billing Requirements.--The home health services included in the consolidated billing governing home health PPS are:

- Part-time or intermittent skilled nursing services;
- Part-time or intermittent home health aide services;
- Physical therapy;
- Speech-language pathology services;
- Occupational therapy;
- Medical social services;
- Routine and non-routine medical supplies;
- Covered osteoporosis drug as defined in §1861(kk) of the Act, but excluding other drugs and biologicals;
- Medical services provided by an intern or resident in-training of the program of the hospital in the case of an HHA that is affiliated or under common control with a hospital with an approved teaching program; and

- Home health services defined in §1861(m) provided under arrangement at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the home or are furnished while the patient is at the facility to receive such services.

B. Medical Supplies.--The law requires all medical supplies (routine and non-routine) bundled to the agency while the patient is under a home health plan of care. The agency that establishes the episode is the only entity that can bill and receive payment for medical supplies during an episode for a patient under a home health plan of care. Both routine and non-routine medical supplies are included in the base rates for every Medicare home health patient regardless of whether or not the patient requires medical supplies during the episode. Due to the consolidated billing requirements, we provided additional amounts in the base rates for those non-routine medical supplies that have a duplicate Part B code that could have been unbundled to Part B prior to PPS. See §206.4 for detailed discussion of medical supplies.

Medical supplies used by the patient, provider, or other practitioners under arrangement on behalf of the agency (other than physicians) are subject to consolidated billing and bundled to the HHA episodic payment rate. Once a patient is discharged from home health and not under a home health plan of care, the HHA is not responsible for medial supplies.

DME, including supplies covered as DME, are paid separately from the PPS rates and are excluded from the consolidated billing requirements governing PPS. The determining factor is the medical classification of the supply, not the diagnosis of the patient. For example, infusion therapy will continue to be covered under the DME benefit separately paid from the PPS rate and excluded from the consolidated billing requirements governing PPS. The DME supplies that are currently covered and paid in accordance with the DME fee schedule as category SU are billed under the DME benefit and not included in the bundled HHA episodic payment rate. The HHAs are not required to do consolidated billing of SU supplies.

Osteoporosis drugs are included in consolidated billing under the home health benefit. However, payment is not bundled into the episodic payment rate. The HHAs must bill for osteoporosis drugs in accordance with billing instructions. Payment is in addition to the episodic payment rate.

C. Relationship Between Consolidated Billing Requirements and Part B Supplies and Part B Therapies Included in the Baseline Rates That Could Have Been Unbundled Prior to PPS That No Longer Can Be Unbundled.--The HHA is responsible for the services provided under arrangement on their behalf by other entities. Covered home health services at §1861(m) of the Act (except DME) are included in the baseline PPS rates and subject to the consolidated billing requirements while the patient is under a plan of care of the HHA. The time the services are bundled is while the patient is under a home health plan of care.

Physician services or nurse practitioner services that are bundled into the physician fee schedule payments are not recognized as a home health service included in the PPS rate. Supplies incident to a physician service or related to a physician service billed to the carrier are not subject to the consolidated billing requirements. The physician would not be acting as a supplier billing the DMERC in this situation.

Therapies (physical therapy, occupational therapy, and speech-language pathology services) are covered home health services that are included in the baseline rates and subject to the consolidated billing requirements. In addition to therapies that had been paid on a cost basis under home health, we have included in the final rates additional amounts for Part B therapies that could have been unbundled prior to PPS, these therapies are subject to the consolidated billing requirements. There are revenue center codes that reflect the ranges of outpatient physical therapy, occupational therapy, and speech-language pathology services and HCPCs codes that reflect physician supplier codes that

are physical therapy, occupational therapy, and speech-language pathology services by code definition and are subject to the consolidated billing requirements. Therefore, the above mentioned therapies must be provided directly or under arrangement on behalf of the HHA while a patient is under a home health plan of care cannot be separately billed to Part B during an open 60 day episode.

D. Freedom of Choice Issues.--A beneficiary exercises his or her freedom of choice for the services under the home health benefit listed in §1861(m) of the Act, including medical supplies, but excluding DME covered as a home health service by choosing the HHA. Once a home health patient chooses a particular HHA, he or she has clearly exercised freedom of choice with respect to all items and services included within the scope of the Medicare home health benefit (except DME). The HHA's consolidated billing role supersedes all other billing situations the beneficiary may wish to establish for home health services covered under the scope of the Medicare home health benefit during the certified episode.

E. Knowledge of Services Arranged for on Behalf of the HHA.--The consolidated billing requirements governing home health PPS requires that the HHA provide all covered home health services (except DME) either directly or under arrangement while a patient is under a home health plan of care. Providing services either directly or under arrangement requires knowledge of the services provided during the episode. In addition, in accordance with current Medicare conditions of participation and Medicare coverage guidelines governing home health, the patient's plan of care must reflect the physician ordered services that the HHA provides either directly or under arrangement. An HHA would not be responsible for payment in the situation in which they have no prior knowledge of the services provided by an entity during an episode to a patient who is under their home health plan of care. An HHA is responsible for payment in the situation in which services are provided to a patient by another entity, under arrangement with the HHA, during an episode in which the patient is under the HHA's home health plan of care. However, it is in the best interest of future business relationships to discuss the situation with any entity that seeks payment from the HHA during an episode in an effort to resolve any misunderstanding and avoid such situations in the future.

201.13 Telehealth.--An HHA may adopt telehealth technologies that it believes promote efficiencies or improve quality of care. Telehomecare encounters do not meet the definition of a visit set forth in regulations at 42 CFR 409.48(c) and the telehealth services may not be counted as Medicare covered home health visits or used as qualifying services for home health eligibility. An HHA may not substitute telehealth services for Medicare-covered services ordered by a physician. However, if an HHA has telehealth services available to its clients, a doctor may take their availability into account when he or she prepares a plan of treatment (i.e., may write requirements for telehealth services into the POT). Medicare eligibility and payment would be determined based on the patient's characteristics and the need for and receipt of the Medicare covered services ordered by the physician. If a physician intends that telehealth services be furnished while a patient is under a home health plan of care, the services should be recorded in the plan of care along with the Medicare covered home health services to be furnished.

201.14 Change of Ownership Relationship to Episodes Under PPS.--

A. Change of Ownership With Assignment.--When there is a change of ownership and the new owner accepts assignment of the existing provider agreement, the new owner is subject to all the terms and conditions under which the existing agreement was issued. The provider number remains the same if the new HHA owner accepts assignment of the existing provider agreement. As long as the new owner complies with the regulations governing home health PPS, billing and

payment for episodes with applicable adjustments for existing patients under an established plan of care will continue on schedule through the change in ownership with assignment of provider number. The episode would be uninterrupted spanning the date of sale. The former owner is required to file a terminating cost report. Episodes ending on or before the date of sale would be attributed to the former owner's cost report and the episode ending date after the date of sale would be attributed to the new owner's cost report.

B. Change of Ownership Without Assignment.--When there is a change of ownership and the new owner does not take the assignment of the existing provider agreement, the provider agreement and provider number of the former owner is terminated. The former owner will receive partial episode payment adjusted payments in accordance with the methodology set forth in §484.235 based on the last billable visit date for existing patients under a home health plan of care ending on or before the date of sale. The former owner is required to file a terminating cost report. The new owner cannot bill Medicare for payment until the effective date of the Medicare approval. The new HHA will not be able to participate in the Medicare program without going through the same process as any new provider, which includes an initial survey. Once the new owner is Medicare-approved, the HHA may start a new episode clock for purposes of payment, OASIS assessment, and certification of the home health plan of care for all new patients in accordance with the regulations governing home health PPS, effective with the date of the new provider certification.

C. Change of Ownership-Mergers.--The merger of a provider corporation into another corporation constitutes a change of ownership. In the case of a merger of Agency A into Agency B, Agency A's provider agreement and its provider number are terminated. Agency B retains its existing provider agreement and provider number. The former owner (Agency A) will receive partial episode payment adjusted payments in accordance with the methodology set forth in §484.235 based on the last billable visit date for existing patients under a home health plan of care ending on or before the date of sale. The former owner (Agency A) is required to file a terminating cost report. The surviving HHA (Agency B) must start a new episode for payment, OASIS assessment and certification of the home health plan of care for all patients admitted after the merger, including former patients of Agency A, at the next skilled visit after the official merger date.

Covered and Noncovered Home Health Services

203. CONDITIONS TO BE MET FOR COVERAGE OF HOME HEALTH SERVICES

Home health agency (HHA) services are covered by Medicare when the following criteria are met:

- The person to whom the services are provided is an eligible Medicare beneficiary.
- The HHA that is providing the services to the beneficiary has in effect a valid agreement to participate in the Medicare program.
- The beneficiary qualifies for coverage of home health services as described in §204.
- The services for which payment is claimed are covered as described in §§205 and 206.
- Medicare is the appropriate payer.
- The services for which payment is claimed are not otherwise excluded from payment.

203.1 Reasonable and Necessary Services.--

A. Background.--In enacting the Medicare program, Congress recognized that the physician would play an important role in determining utilization of services. The law requires that payment may be made only if a physician certifies the need for services and establishes a plan of care. The Secretary is responsible for ensuring that the claimed services are covered by Medicare, including determining whether they are "reasonable and necessary."

B. Determination of Coverage.--The intermediary's decision on whether care is reasonable and necessary is based on information reflected in the home health plan of care (Form CMS-485) and supplementary forms (e.g., comprehensive assessment including the OASIS as required by 42 CFR 484.55 or an HHA's internal form), and the medical record concerning the unique medical condition of the individual patient. 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 patient's individual need for care. Additional information from the medical record must be requested when medical information needed to support a decision is not clearly present. The following examples illustrate this statement.

Examples of cases in which development of the case is needed:

EXAMPLE 1: A plan of care provides for daily skilled nursing visits for care of a pressure sore, but the description of the pressure sore and the dressing that is on the form causes the reviewer to question why daily skilled care is needed. The intermediary would not reduce the number of visits but would either request additional information to support the need for daily care or would request the nursing notes to determine if the patient required daily skilled care.

EXAMPLE 2: A patient with a diagnosis of congestive heart failure (CHF) has been hospitalized for 5 days. Posthospital skilled nursing care is ordered 3 x wk x 60 days for skilled observation, teaching of diet medication compliance and signs and symptoms of the disease. The documentation on the Form CMS 485 and supplementary form shows that the patient has had CHF for 10 years with an exacerbation requiring recent hospitalization. The medications are not shown as

changed or new. The clinical findings are contradictory. There is a possibility that this patient requires skilled observation and teaching although the documentation does not give a clear picture of the patient's needs. Therefore, the case would be developed further to determine if the criteria for coverage were met.

Examples of cases that would be denied without further development:

EXAMPLE 3: A plan of care provides for vitamin B-12 injections 1 x mo x 60 days for a patient who has been discharged from the hospital following a recent hip fracture. The patient has generalized weakness, but there is no diagnosis or clinical symptoms shown to support Medicare coverage of skilled nursing care for B-12 injections. The claim would be denied without further development.

EXAMPLE 4: A patient has a primary diagnosis of back sprain that resulted in a 7-day hospitalization. The patient also has a secondary diagnosis of emphysema with an onset 2 years prior to the start of care. Following the hospitalization, the physician ordered skilled nursing 2 x wk x 4 weeks for skilled observation of vital signs and response to medication and aide services 2 x wk x 4 weeks for personal care. The documentation on the **Form CMS 485** and supplementary form shows that the patient is up as tolerated, able to walk 10 feet without resting, and able to perform ADLs. Clinical facts show normal vital signs with no reference to emphysema. The patient is on colace 100 mg BID. The documentation clearly does not support the medical necessity for skilled nursing care and the claim for the services would be denied without development.

Examples of cases in which payment may be made without further development:

EXAMPLE 5: A patient with a diagnosis of CHF has been hospitalized for five days. Post-hospital skilled nursing care is ordered 3 x wk x 60 days for skilled observation, teaching of a new diet regimen, compliance with multiple new medications, and signs and symptoms of the disease state. The documentation on the **Form CMS-485** and supplementary form shows the patient has had an acute exacerbation of a pre-existing CHF condition that required the recent acute hospitalization. The patient is discharged from the hospital with a medication regimen changed from previous medications. The CMS forms documenting the clinical evidence of the recent acute exacerbation of the patient's cardiac condition combined with changed medications support the physician's order for care. Payment may be made without further development.

EXAMPLE 6: A plan of care provides for physical therapy treatments 3 x wk x 45 days for a patient who has been discharged from the hospital following a recent hip fracture. The patient was discharged using a walker 7 days before the start of home care. The **Form CMS-485** and supplementary form show that the patient was discharged from the hospital with restricted mobility in ambulation, transfers, and climbing of stairs. The patient had an unsafe gait indicating a need for gait training and had not been instructed in stair climbing and a home exercise program. The goal of the physical therapy was to increase strength, range of motion and to progress from walker to cane with safe gait. Information on the relevant CMS forms also indicates that the patient had a previous functional capacity of full ambulation, mobility, and self care. The claim may be paid without further development, since there are no objective clinical factors in the medical evidence to contradict the order of the patient's treating physician.

203.2 Impact of Other Available Caregivers and Other Available Coverage on Medicare Coverage of Home Health Services.--Where the Medicare criteria for coverage of home health services are met, patients are entitled by law to coverage of reasonable and necessary home health services. Therefore, a patient is entitled to have the reasonable and necessary services reimbursed by Medicare without regard to whether there is someone available to furnish the services. However, where a family member or other person is or will be providing services that adequately meet the patient's needs, it would not be reasonable and necessary for HHA personnel to furnish such services. Ordinarily it can be presumed that there is no able and willing person to provide the services being rendered by the HHA unless the patient or family indicates otherwise and objects to the provision of the services by the HHA, or the HHA has first hand knowledge to the contrary.

EXAMPLE: A patient, who lives with an adult daughter and otherwise qualifies for Medicare coverage of home health services, requires the assistance of a home health aide for bathing and assistance with an exercise program to improve endurance. The daughter is unwilling to bathe her elderly father and assist with the exercise program. Home health aide services to provide these services would be reasonable and necessary.

Similarly, a patient is entitled to have the reasonable and necessary home health services reimbursed by Medicare even if the patient would qualify for institutional care (e.g., hospital care or skilled nursing facility care).

EXAMPLE: A patient who is discharged from a hospital with a diagnosis of osteomyelitis and requires continuation of the IV antibiotic therapy that was begun in the hospital was found to meet the criteria for Medicare coverage of skilled nursing facility services. If the patient also meets the qualifying criteria for coverage of home health services, payment may be made for the reasonable and necessary home health services the patient needs, notwithstanding the availability of coverage in a skilled nursing facility.

Medicare payment should be made for reasonable and necessary home health services where the patient is also receiving supplemental services that do not meet Medicare's definition of skilled nursing care or home health aide services.

EXAMPLE: A patient who needs skilled nursing care on an intermittent basis also hires a licensed practical (vocational) nurse to provide nighttime assistance while family members sleep. The care provided by the nurse, as respite to the family members, does not require the skills of a licensed nurse as defined in §205.1 and, therefore, has no impact on the patient's eligibility for Medicare payment of home health services even though another third party insurer may pay for that nursing care.

203.3 Use of Utilization Screens and "Rules of Thumb".--Medicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each patient's individual care needs. Therefore, denial of services based on numerical utilization screens, diagnostic screens, diagnosis or specific treatment norms is not appropriate.

204. CONDITIONS THE PATIENT MUST MEET TO QUALIFY FOR COVERAGE OF HOME HEALTH SERVICES

To qualify for Medicare coverage of any home health services, the patient must meet each of the criteria described in this section. Patients who meet each of these criteria are eligible to have payment made on their behalf for the services discussed in §§205 and 206.

204.1 Confined to the Home.--

A. Patient Confined to The Home.--In order for a patient to be eligible to receive covered home health services under both Part A and Part B, the law requires that a physician certify in all cases that the patient is confined to his/her home. (See §240.1.) An individual does not have to be bedridden to be considered as confined to the home. However, the condition of these patients should be such that there exists a normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort. If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive **health care treatment**. Absences attributable to the need to receive **health care treatment** include, **but are not limited to**, attendance at adult day centers to receive medical care, ongoing receipt of outpatient kidney dialysis, and the receipt of outpatient chemotherapy or radiation therapy. **Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in a State shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.** It is expected that in most instances, absences from the home that occur will be for the purpose of receiving **health care treatment**. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block or a drive, would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

Generally speaking, a patient will be considered to be homebound if he/she has a condition due to an illness or injury that restricts his/her ability to leave his/her place of residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers, the use of special transportation, or the assistance of another person or if leaving home is medically contraindicated. Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists would be: (1) a patient paralyzed from a stroke who is confined to a wheelchair or requires the aid of crutches in order to walk; (2) a patient who is blind or senile and requires the assistance of another person to leave his/her residence; (3) a patient who has lost the use of his/her upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and requires the assistance of another individual to leave his/her residence; (4) a patient who has just returned from a hospital stay involving surgery suffering from resultant weakness and pain and, therefore, his/her actions may be restricted by his/her physician to certain specified and limited activities such as getting out of bed only for a specified period of time, walking stairs only once a day, etc.; (5) a patient with arteriosclerotic heart disease of such severity that he/she must avoid all stress and physical activity; and (6) a patient with a psychiatric problem if the illness is manifested in part by a refusal to leave home or is of such a nature that it would not be considered safe to leave home unattended, even if he/she has no physical limitations.

The aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age would not be considered confined to the home for purposes of receiving home health services unless he/she meets one of the above conditions. A patient who requires skilled care must also be determined to be confined to the home in order for home health services to be covered.

Although a patient must be confined to the home to be eligible for covered home health services, some services cannot be provided at the patient's residence because equipment is required that cannot be made available there. If the services required by a patient involve the use of such equipment, the HHA may make arrangements **or contract** with a hospital, skilled nursing facility,

or a rehabilitation center to provide these services on an outpatient basis. (See §§200.2 and 206.5.) However, even in these situations, for the services to be covered as home health services, the patient must be considered confined to his/her home; and to receive such outpatient services a homebound patient will generally require the use of supportive devices, special transportation, or the assistance of another person to travel to the appropriate facility.

If a question is raised as to whether a patient is confined to the home, the HHA will be asked to furnish the intermediary with the information necessary to establish that the patient is homebound as defined above.

B. Patient's Place of Residence.--A patient's residence is wherever he/she makes his/her home. This may be his/her own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution. However, an institution may not be considered a patient's home if the institution meets the requirements of §§1861(e)(1) or 1819 (a)(1) of the Act. Included in this group are hospitals and skilled nursing facilities, as well as most nursing facilities under Medicaid.

Thus, if a patient is in an institution or distinct part of an institution identified above, the patient is not entitled to have payment made for home health services under either Part A or Part B since these institutions may not be considered his/her residence. When a patient remains in a participating SNF following his/her discharge from active care, the facility may not be considered his/her residence for purposes of home health coverage.

A patient may have more than one home and the Medicare rules do not prohibit a patient from having one or more places of residence. A patient, under a Medicare home health plan of care, who resides in more than one place of residence during an episode of Medicare covered home health services will not disqualify the patient's homebound status for purposes of eligibility. For example, a person may reside in a principal home and also a second vacation home, mobile home or the home of a caretaker relative. The fact that the patient resides in more than one home and, as a result, must transit from one to the other, is not in itself, an indication that the patient is not homebound. The requirements of homebound must be met at each location (e.g., considerable taxing effort etc).

1. Assisted Living Facilities, Group Homes & Personal Care Homes.--An individual may be "confined to the home" for purposes of Medicare coverage of home health services if he or she resides in an institution that is not primarily engaged in providing to inpatients diagnostic and therapeutic services for medical diagnosis, treatment, care of disabled or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, or skilled nursing care or related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, sick, or disabled persons. If it is determined that the assisted living facility (also called personal care homes, group homes, etc.) in which the individuals reside are not primarily engaged in providing the above services, then Medicare will cover reasonable and necessary home health care furnished to these individuals.

If it is determined that the services furnished by the home health agency are duplicative of services furnished by an assisted living facility (also called personal care homes, group homes, etc.) when provision of such care is required of the facility under State licensure requirements, claims for such services should be denied under §1862(a)(1)(A) of the Act. Section 1862(a)(1)(A) excludes services that are not necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member from Medicare coverage. Services to people who already have access to appropriate care from a willing caregiver would not be considered to be reasonable and necessary to the treatment of the individual's illness or injury.

From the Medicare perspective, individuals who reside in assisted living facilities may be eligible for coverage of Medicare home health services. A major consideration is the location of the individual within the assisted living facility in terms of the level and type of care that is provided.

Medicare coverage would not be an optional substitute for the services that a facility that is required to provide by law to its patients or where the services are included in the base contract of the facility. An individual's choice to reside in such a facility is also a choice to accept the services it holds itself out as offering to its patients.

2. Day Care Centers and Patient's Place of Residence.--The law does not permit an HHA to furnish a Medicare covered billable visit to a patient under a home health plan of care outside his or her home, except in those limited circumstances where the patient needs to use medical equipment that is too cumbersome to bring to the home. Section 507 of the Medicare, Medicaid and SCHIP Beneficiary Improvement and Protection Act (BIPA) of 2000 amended §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act governing home health eligibility. The new law did not amend §1861(m) of the Act governing coverage. Section 1861(m) of the Act stipulates that home health services provided to a patient be provided to the patient on a visiting basis in a place of residence used as the individual's home. A licensed/certified day care center does not meet the definition of a place of residence.

3. State Licensure/Certification of Day Care Facilities.--In order to meet the requirements of §507 of BIPA, an adult day care center must be either licensed or certified by the State or accredited by a private accrediting body. State licensure or certification as an adult day care facility must be based on State interpretations of its process. For example, we understand that several States do not license adult day care facilities as a whole, but do certify some entities as Medicaid certified centers for purposes of providing adult day care under the Medicaid home and community based waiver program. We believe that it is the responsibility of the State to determine the necessary criteria for "State certification" in such a situation. A State could determine that Medicaid certification is an acceptable standard and consider its Medicaid certified adult day care facilities to be "State certified". On the other hand, a State could determine Medicaid certification to be insufficient and require other conditions to be met before the adult day care facility is considered "State certified".

4. Determination of the Therapeutic, Medical or Psychosocial Treatment of the Patient at the Day Care Facility.--We do not believe it is the obligation of the HHA to determine whether the adult day care facility is providing psychosocial treatment, but only to assure that the adult day care center is licensed/certified by the State or accrediting body. We believe that the intent of the law, in extending the homebound exception status to attendance at such adult day care facilities, recognizes that they ordinarily furnish psychosocial services.

204.2 Services Are Provided Under a Plan of Care Established and Approved by a Physician.--

A. Content of the Plan of Care.--The plan of care must contain all pertinent diagnoses, including the patient's mental status, the types of services, supplies, and equipment required, the frequency of visits to be made, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, all medications and treatments, safety measures to protect against injury, instructions for timely discharge or referral, and any additional items the HHA or physician choose to include.

NOTE: This manual uses the term "plan of care" to refer to the medical treatment plan established by the treating physician with the assistance of the home health care nurse. Although CMS previously used the term "plan of treatment," the Omnibus Budget Reconciliation Act of 1987 replaced that term with "plan of care" without a change in definition. CMS anticipates that a discipline-oriented plan of care will be established, where appropriate, by an HHA nurse regarding nursing and home health aide services and by skilled therapists regarding specific therapy treatment. These **care plans** may be incorporated in the physician's plan of care or separately prepared.

B. Specificity of Orders.--The orders on the plan of care must specify the type of services to be provided to the patient, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services.

EXAMPLE: SN x 7/wk x 1 wk; 3/wk x 4 wk; 2/wk x 3 wk, (skilled nursing visits 7 times per week for 1 week; three times per week for 4 weeks; and two times per week for 3 weeks) for skilled observation and evaluation of the surgical site, for teaching sterile dressing changes and to perform sterile dressing changes. The sterile change consists of (detail of procedure).

Orders for care may indicate a specific range in the frequency of visits to ensure that the most appropriate level of service is provided **during the 60 day episode** to home health patients. When a range of visits is ordered, the upper limit of the range is considered the specific frequency.

EXAMPLE: SN x 2-4/wk x 4 wk; 1-2/wk x 4 wk for skilled observation and evaluation of the surgical site. . . .

Orders for services to be furnished "as needed" or "PRN" must be accompanied by a description of the patient's medical signs and symptoms that would occasion a 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.

C. Who Signs the Plan of Care.--The physician who signs the plan of care must be qualified to sign the physician certification as described in 42 CFR 424.22.

D. Timeliness of Signature.--

1. Initial Percentage Payment.--If a physician signed plan of care is not available at the beginning of the episode, the HHA may submit a RAP for the initial percentage payment based on physician verbal orders OR a referral prescribing detailed orders for the services to be rendered that is signed and dated by the physician. If the RAP submission is based on physician verbal orders, the verbal order must be recorded in the plan of care, include a description of the patient's condition and the services to be provided by the home health agency, include an attestation (relating to the physician's orders and the date received per 42 CFR 409.43), and the plan of care is copied and immediately submitted to the physician. A billable visit must be rendered prior to the submission of a RAP.

2. Final Percentage Payment.--The plan of care must be signed and dated by a physician as described who meets the certification and recertification requirements of §424.22 and before the claim for each episode for services is submitted for the final percentage payment. Any changes in the plan of care must be signed and dated by a physician.

E. Use of Oral (Verbal) Orders.--When services are furnished based on a physician's oral order, the orders may be accepted and put in writing by personnel authorized to do so by applicable State and Federal laws and regulations, as well as by the HHA's internal policies. The orders must be signed and dated with the date of receipt by the registered nurse or qualified therapist (i.e., physical therapist, speech-language pathologist, occupational therapist, or medical social worker) responsible for furnishing or supervising the ordered services. The orders may be signed by the supervising registered nurse or qualified therapist after the services have been rendered, as long as HHA personnel who receive the oral orders notify that nurse or therapist before the service is rendered. Thus, the rendering of a service that is based on an oral order would not be delayed pending signature of the supervising nurse or therapist. Oral orders must be countersigned and dated by the physician before the HHA bills for the care in the same way as the plan of care.

(1) Services that are provided from the beginning of the 60 day episode certification period based on a request for anticipated payment and before the physician signs the plan of care are considered to be provided under a plan of care established and approved by the physician where there is an oral order for the care prior to rendering the services which is documented in the medical record and where the services are included in a signed plan of care.

EXAMPLE: The HHA acquires an oral order for IV medication administration for a patient to be performed on August 1. The HHA provides the IV medication administration August 1 and evaluates the patient's need for continued care. The physician signs the plan of care for the IV medication administration on August 15. Since the HHA had acquired an oral order prior to the delivery of services, the visit is considered to be provided under a plan of care established and approved by the physician.

(2) Services that are provided in the subsequent 60 day episode certification period are considered to be provided under the plan of care of the subsequent 60 day episode where there is an oral order before the services provided in the subsequent period are furnished and the order is reflected in the medical record. However, services that are provided after the expiration of a plan of care, but before the acquisition of an oral order or a signed plan of care, cannot be considered to be provided under a plan of care.

EXAMPLE 1: The patient is under a plan of care in which the physician orders IV medication administration every 2 weeks. The last day covered by the initial plan of care is July 31. The patient's next IV medication administration is scheduled for August 5th and the physician signs the plan of care for the new period on August 1st. The IV medication administration on August 5th was provided under a plan of care established and approved by the physician. The episode begins on the 61st day regardless of the date of the first covered visit.

EXAMPLE 2: The patient is under a plan of care in which the physician orders IV medication administration every 2 weeks. The last day covered by the plan of care is July 31. The patient's next IV medication administration is scheduled for August 5th and the physician does not sign the plan of care until August 6th. The HHA acquires an oral order for the IV medication administration before the August 5th visit, and therefore the visit is considered to be provided under a plan of care established and approved by the physician. The episode begins on the 61st day regardless of the date of the first covered visit.

(3) Any increase in the frequency of services or addition of new services during a certification period must be authorized by a physician by way of a written or oral order prior to the provision of the increased or additional services.

F. Frequency of Review of the Plan of Care.--The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with HHA professional personnel, at least every 60 days. Each review of a patient's plan of care must contain the signature of the physician and the date of review.

G. Facsimile Signatures.--The plan of care or oral order may be transmitted by facsimile machine. The HHA is not required to have the original signature on file. However, the HHA is responsible for obtaining original signatures if an issue surfaces that would require verification of an original signature

H. Alternative Signatures.--HHAs that maintain patient records by computer rather than hard copy may use electronic signatures. However, all such entries must be appropriately authenticated and dated. Authentication must include signatures, written initials, or computer secure entry by a unique identifier of a primary author who has reviewed and approved the entry. The HHA must have safeguards to prevent unauthorized access to the records and a process for reconstruction of the records in the event of a system breakdown.

I. Termination of the Plan of Care.--The plan of care is considered to be terminated if the patient does not receive at least one covered skilled nursing, physical therapy, speech-language pathology service, or occupational therapy visit in a 60-day period unless the physician documents that the interval without such care is appropriate to the treatment of the patient's illness or injury.

J. Sequence of Qualifying Services and Other Medicare Covered Home Health Services.--Once patient eligibility has been confirmed and the plan of care contains physician orders for the qualifying service as well as other Medicare covered home health services, the qualifying service does not have to be rendered prior to the other Medicare covered home health services ordered in the plan of care. The sequence of visits performed by the disciplines must be dictated by the individual patient's plan of care. For example, for an eligible patient in an initial 60-day episode that has both physical therapy and occupational therapy orders in the plan of care, the sequence of the delivery of the type of therapy is irrelevant as long as the need for the qualifying service is established prior to the delivery of other Medicare covered services and the qualifying discipline provides a billable visit prior to transfer or discharge in accordance with 42 CFR 409.43(f).

204.3 Under the Care of a Physician.--The patient must be under the care of a physician who is qualified to sign the physician certification and plan of care in accordance with 42 CFR 424.22.

A patient is expected to be under the care of the physician who signs the plan of care and the physician certification. It is expected, but not required for coverage, that the physician who signs the plan of care will see the patient, but there is no specified interval of time within which the patient must be seen.

204.4 Needs Skilled Nursing Care on an Intermittent Basis (Other than Solely Venipuncture for the Purposes of Obtaining a Blood Sample) or Physical Therapy or Speech-Language Pathology Services or Has Continued Need for Occupational Therapy.--The patient must need one of the following types of skilled services:

- Skilled nursing care that:
 - Is reasonable and necessary as defined in §§205.1A and B,
 - Is needed on an "intermittent" basis as defined in §205.1C, and
 - Is not solely needed for venipuncture for the purposes of obtaining a blood sample as defined in §205.1, or
- Physical therapy as defined in §§205.2A and B, or
- Speech-language pathology services as defined in §§205.2A and C, or
- A continuing need for occupational therapy as defined in §§205.2A and D.
- The patient has a continued need for occupational therapy when:
 - The services that the patient requires meet the definition of "occupational therapy" services of §§205.2A and D, and

- The patient's eligibility for home health services has been established by virtue of a prior need for skilled nursing care (**other than solely venipuncture for the purposes of obtaining a blood sample**), speech-language pathology services, or physical therapy in the current or prior certification period.

EXAMPLE: A patient who is recovering from a cerebral vascular accident has an initial plan of care that called for physical therapy, speech-language pathology services, and home health aide services. In the next certification period, the physician orders only occupational therapy and home health aide services because the patient no longer needs the skills of a physical therapist or a speech-language pathologist, but needs the services provided by the occupational therapist. The patient's need for occupational therapy qualifies him or her for home health services, including home health aide services (presuming that all other qualifying criteria are met).

204.5 Physician Certification.--The HHA must be acting upon a physician certification that is part of the plan of care (**Form CMS-485**) and meets the requirements of this section for HHA services to be covered.

A. Content of the Physician Certification.--The physician must certify that:

1. The home health services are or were needed because the patient is or was confined to the home as defined in §204.1;

2. The patient needs or needed skilled nursing services on an intermittent basis (**other than solely venipuncture for the purposes of obtaining a blood sample**), physical therapy, or speech-language pathology services, or continues or continued to need occupational therapy after the need for skilled nursing care, physical therapy, or speech-language pathology services ceased;

3. A plan of care has been established and is periodically reviewed by a physician; and

4. The services are or were furnished while the patient is or was under the care of a physician.

B. Periodic Recertification.--The physician certification may cover a period less than but not greater than **60** days.

C. Who May Sign the Certification.--The physician who signs the certification must be permitted to do so by 42 CFR 424.22.

205. COVERAGE OF SERVICES WHICH ESTABLISH HOME HEALTH ELIGIBILITY

For any home health services to be covered by Medicare, the patient must meet the qualifying criteria as specified in §204, including having a need for skilled nursing care on an intermittent basis (**other than solely venipuncture for the purposes of obtaining a blood sample**), physical therapy, speech-language pathology services, or a continuing need for occupational therapy as defined in this section.

205.1 Skilled Nursing Care.--To be covered as skilled nursing services, the services must require the skills of a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury as discussed in §§205.1A and B, and must be intermittent as discussed in §205.1C.

10. Heat Treatments.--Heat treatments that have been specifically ordered by a physician as part of active treatment of an illness or injury and require observation by a licensed nurse to adequately evaluate the patient's progress would be considered as skilled nursing services.

11. Medical Gasses.--Initial phases of a regimen involving the administration of medical gasses that are necessary to the treatment of the patient's illness or injury, would require skilled nursing care for skilled observation and evaluation of the patient's reaction to the gasses and to teach the patient and family when and how to properly manage the administration of the gasses.

12. Rehabilitation Nursing.--Rehabilitation nursing procedures, including the related teaching and adaptive aspects of nursing that are part of active treatment (e.g., the institution and supervision of bowel and bladder training programs) would constitute skilled nursing services.

13. Venipuncture.--Effective February 2, 1998, as mandated by the Balanced Budget Act (BBA) of 1997, venipuncture for the purposes of obtaining a blood sample can no longer be the sole reason for Medicare home health eligibility. However, if a beneficiary qualifies for home health eligibility based on a skilled need other than solely venipuncture (e.g., eligibility based on the skilled nursing service of wound care and meets all other Medicare home health eligibility criteria), medically reasonable and necessary venipuncture coverage may continue during the 60 day episode under a home health plan of care. Venipuncture when the collection of the specimen is necessary to the diagnosis and treatment of the patient's illness or injury and when the venipuncture cannot be performed in the course of regularly scheduled absences from the home to acquire medical treatment is a skilled nursing service. The frequency of visits for venipuncture must be reasonable within accepted standards of medical practice for treatment of the illness or injury.

For venipuncture to be reasonable and necessary:

- The physician order for the venipuncture for a laboratory test should be associated with a specific symptom or diagnosis or the documentation should clarify the need for the test when it is not diagnosis/illness specific. In addition, the treatment must be recognized (in the Physician's Desk Reference or other authoritative source) as being reasonable and necessary to the treatment of the illness or injury for venipuncture for monitoring the treatment to be reasonable and necessary.

- The frequency of testing should be consistent with accepted standards of medical practice for continued monitoring of a diagnosis, medical problem or treatment regimen. Even where the laboratory results are consistently stable, periodic venipuncture may be reasonable and necessary because of the nature of the treatment.

Examples of reasonable and necessary venipuncture for stabilized patients include, but are not limited to those described below. While these guidelines do not preclude a physician from ordering more frequent venipuncture for these laboratory tests, the HHA must present justifying documentation to support the reasonableness and necessity of more frequent testing.

a. Captopril may cause side effects such as leukopenia and agranulocytosis and it is standard medical practice to monitor the white blood cell count and differential count on a routine basis (every 3 months) when the results are stable and the patient is asymptomatic.

b. In monitoring phenytoin (e.g., Dilantin) administration, the difference between a therapeutic and a toxic level of phenytoin in the blood is very slight. Therefore, it is appropriate to monitor the level on a routine basis (every 3 months) when the results are stable and the patient is asymptomatic.

c. Venipuncture for fasting blood sugar (FBS):

- An unstable insulin dependent or non-insulin dependent diabetic would require FBS more frequently than once per month if ordered by the physician.

- Where there is a new diagnosis or there has been a recent exacerbation, but the patient is not unstable, monitoring once per month would be reasonable and necessary.

- A stable insulin or non-insulin dependent diabetic would require monitoring every 2-3 months.

d. Venipuncture for prothrombin

- Where the documentation shows that the dosage is being adjusted, monitoring would be reasonable and necessary as ordered by the physician.

- Where the results are stable within the therapeutic ranges, monthly monitoring would be reasonable and necessary.

- Where the results are stable within non-therapeutic ranges, there must be documentation of other factors that would indicate why continued monitoring is reasonable and necessary.

EXAMPLE: A patient with coronary artery disease was hospitalized with atrial fibrillation and was subsequently discharged to the HHA with orders for anticoagulation therapy. Monthly venipuncture as indicated are necessary to report prothrombin (protime) levels to the physician, notwithstanding that the patient's prothrombin time tests indicate essential stability.

14. Student Nurse Visits.--Visits made by a student nurse may be covered as skilled nursing care when the HHA participates in training programs that utilize student nurses enrolled in a school of nursing to perform skilled nursing services in a home setting. To be covered, the services must be reasonable and necessary skilled nursing care and must be performed under the general supervision of a registered or licensed nurse. The supervising nurse need not accompany the student nurse on each visit.

15. Psychiatric Evaluation, Therapy, and Teaching.--The evaluation, psychotherapy, and teaching activities needed by a patient suffering from a diagnosed psychiatric disorder that requires active treatment by a psychiatrically trained nurse and the costs of the psychiatric nurse's services may be covered as a skilled nursing service. Psychiatrically trained nurses are nurses who have special training and/or experience beyond the standard curriculum required for a registered nurse. The services of the psychiatric nurse are to be provided under a plan of care established and reviewed by a physician.

Because the law precludes agencies that primarily provide care and treatment of mental diseases from participating as HHAs, psychiatric nursing must be furnished by an agency that does not primarily provide care and treatment of mental diseases. If a substantial number of an HHA's patients attend partial hospitalization programs or receive outpatient mental health services, the intermediary may verify whether the patients meet the eligibility requirements specified in §204 and whether the HHA is primarily engaged in care and treatment of mental diseases.

Services of a psychiatric nurse would not be considered reasonable and necessary to assess or monitor use of psychoactive drugs that are being used for nonpsychiatric diagnoses or to monitor the condition of a patient with a known psychiatric illness who is on treatment but is considered stable. A person on treatment would be considered stable if their symptoms were absent or minimal or if symptoms were present but were relatively stable and did not create a significant disruption in the patient's normal living situation.

EXAMPLE 1: A patient is homebound for medical conditions, but has a psychiatric condition for which he has been receiving medication. The patient's psychiatric condition has not required a change in medication or hospitalization for over 2 years. During a visit by the nurse, the patient's spouse indicates that the patient is awake and pacing most of the night and has begun ruminating about perceived failures in life. The nurse observes that the patient does not exhibit an appropriate level of hygiene and is dressed inappropriately for the season. The nurse comments to the patient about her observations and tries to solicit information about the patient's general medical condition and mental status. The nurse advises the physician about the patient's general medical condition and the new symptoms and changes in the patient's behavior. The physician orders the nurse to check blood levels of medication used to treat the patient's medical and psychiatric conditions. The physician then orders the psychiatric nursing service to evaluate the patient's mental health and communicate with the physician about whether additional intervention to deal with the patient's symptoms and behaviors is warranted.

EXAMPLE 2: A patient is homebound after discharge following hip replacement surgery and is receiving skilled therapy services for range of motion exercise and gait training. In the past, the patient had been diagnosed with clinical depression and was successfully stabilized on medication. There has been no change in her symptoms. The fact that the patient is taking an antidepressant does not indicate a need for psychiatric nursing services.

EXAMPLE 3: A patient was discharged after 2 weeks in a psychiatric hospital with a new diagnosis of major depression. The patient remains withdrawn, in bed most of the day, refusing to leave home. The patient has a depressed affect and continues to have thoughts of suicide, but is not considered to be suicidal. Psychiatric nursing is necessary for supportive interventions until antidepressant blood levels are reached and the suicidal thoughts are diminished further, to monitor suicide ideation, ensure medication compliance and patient safety, perform suicidal assessment, and teach crisis management and symptom management to family members.

C. Intermittent Skilled Nursing Care.--The Balanced Budget Act of 1997 provided a definition of intermittent skilled nursing services for purposes of eligibility by providing the following language to §1861(m) of the Act: For purposes of §§1814(a)(2)(C) and 1835(a)(2)(A), "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable). To meet the requirement for "intermittent" skilled nursing care, a patient must have a medically predictable recurring need for skilled nursing services. In most instances, this definition will be met if a patient requires a skilled nursing service at least once every 60 days.

Since the need for "intermittent" skilled nursing care makes the patient eligible for other covered home health services, the intermediary should evaluate each claim involving skilled nursing services furnished less frequently than once every 60 days. In such cases, payment should be made only if documentation justifies a recurring need for reasonable, necessary, and medically predictable skilled nursing services.

There is a possibility that a physician may order a skilled visit less frequently than once every 60 days for an eligible beneficiary if there exists an extraordinary circumstance of anticipated patient need that is documented in the patient's plan of care in accordance with 42 CFR 409.43(b). A skilled visit frequency of less than once every 60 days would only be covered if it is specifically ordered by a physician in the patient's plan of care and is considered to be a reasonable, necessary and medically predictable skilled need for the patient in the individual circumstance.

Where the need for "intermittent" skilled nursing visits is medically predictable but a situation arises after the first visit making additional visits unnecessary, e.g., the patient is institutionalized or dies, the one visit would be paid at the wage adjusted LUPA amount for that discipline type. However, a one-time order; e.g., to give gamma globulin following exposure to hepatitis, would not be considered a need for "intermittent" skilled nursing care since a recurrence of the problem that would require this service is not medically predictable.

Although most patients require services no more frequently than several times a week, Medicare will pay for part-time (as defined in §206.7) medically reasonable and necessary skilled nursing care 7 days a week for a short period of time (2-3 weeks). There may also be a few cases involving unusual circumstances where the patient's prognosis indicates a medical need for daily skilled services beyond 3 weeks. As soon as the patient's physician makes this judgment, which usually should be made before the end of the 3-week period, the HHA must forward medical documentation justifying the need for such additional services and include an estimate of how much longer daily skilled services will be required.

A person expected to need more or less full-time skilled nursing care over an extended period of time; i.e., a patient who requires institutionalization, usually would not qualify for home health benefits.

3. **Gait Training.**--Gait evaluation and training furnished to a patient whose ability to walk has been impaired by neurological, muscular or skeletal abnormality require the skills of a qualified physical therapist and constitute skilled physical therapy and are considered reasonable and necessary if training can be expected to improve materially the patient's ability to walk.

Gait evaluation and training that is furnished to a patient whose ability to walk has been impaired by a condition other than a neurological, muscular or skeletal abnormality would nevertheless be covered where physical therapy is reasonable and necessary to restore the lost function.

EXAMPLE 1: A physician has ordered gait evaluation and training for a patient whose gait has been materially impaired by scar tissue resulting from burns. Physical therapy services to evaluate the patient's gait, establish a gait training program, and provide the skilled services necessary to implement the program would be covered.

EXAMPLE 2: A patient who has had a total hip replacement is ambulatory but demonstrates weakness and is unable to climb stairs safely. Physical therapy would be reasonable and necessary to teach the patient to safely climb and descend stairs.

Repetitive exercises to improve gait, or to maintain strength and endurance and assistive walking are appropriately provided by nonskilled persons and ordinarily do not require the skills of a physical therapist. Where such services are performed by a physical therapist as part of the initial design and establishment of a safe and effective maintenance program, the services would, to the extent that they are reasonable and necessary, be covered.

EXAMPLE: A patient who has received gait training has reached his maximum restoration potential and the physical therapist is teaching the patient and family how to perform safely the activities that are a part of a maintenance program. The visits by the physical therapist to demonstrate and teach the activities (which by themselves do not require the skills of a therapist) would be covered since they are needed to establish the program.

4. **Range of Motion.**--Only a qualified physical therapist may perform range of motion tests and, therefore, such tests are skilled physical therapy.

Range of motion exercises constitute skilled physical therapy only if they are part of an active treatment for a specific disease state, illness, or injury, that has resulted in a loss or restriction of mobility (as evidenced by physical therapy notes showing the degree of motion lost and the degree to be restored). Range of motion exercises unrelated to the restoration of a specific loss of function often may be provided safely and effectively by nonskilled individuals. Passive exercises to maintain range of motion in paralyzed extremities that can be carried out by nonskilled persons do not constitute skilled physical therapy.

However, as indicated in §205.2A4, where there is clear documentation that, because of special medical complications (e.g., susceptible to pathological bone fractures), the skills of a therapist are needed to provide services that ordinarily do not need the skills of a therapist, then the services would be covered.

5. Maintenance Therapy.--Where repetitive services that are required to maintain function involve the use of complex and sophisticated procedures, the judgement and skill of a physical therapist might be required for the safe and effective rendition of such services. If the judgment and skill of a physical therapist is required to treat the illness or injury safely and effectively, the services would be covered as physical therapy services.

EXAMPLE: Where there is an unhealed, unstable fracture that requires regular exercise to maintain function until the fracture heals, the skills of a physical therapist would be needed to ensure that the fractured extremity is maintained in proper position and alignment during maintenance range of motion exercises.

Establishment of a maintenance program is a skilled physical therapy service where the specialized knowledge and judgement of a qualified physical therapist is required for the program to be safely carried out and the treatment aims of the physician achieved.

EXAMPLE: A Parkinson's patient or a patient with rheumatoid arthritis who has not been under a restorative physical therapy program may require the services of a physical therapist to determine what type of exercises are required to maintain his/her present level of function. The initial evaluation of the patient's needs, the designing of a maintenance program appropriate to the capacity and tolerance of the patient and the treatment objectives of the physician, the instruction of the patient, family or caregivers to carry out the program safely and effectively and such reevaluations as may be required by the patient's condition, would constitute skilled physical therapy.

While a patient is under a restorative physical therapy program, the physical therapist should regularly reevaluate his condition and adjust any exercise program the patient is expected to carry out himself or with the aid of supportive personnel to maintain the function being restored. Consequently, by the time it is determined that no further restoration is possible (i.e., by the end of the last restorative session) the physical therapist will already have designed the maintenance program required and instructed the patient or caregivers in carrying out the program.

6. Ultrasound, Shortwave, and Microwave Diathermy Treatments.--These treatments must always be performed by or under the supervision of a qualified physical therapist and are skilled therapy.

7. Hot Packs, Infra-Red Treatments, Paraffin Baths and Whirlpool Baths.--Heat treatments and baths of this type ordinarily do not require the skills of a qualified physical therapist. However, the skills, knowledge and judgment of a qualified physical therapist might be required in the giving of such treatments or baths in a particular case, e.g., where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures or other complications.

8. Wound Care Provided Within Scope of State Practice Acts.--If wound care falls within the auspice of a physical therapist's State Practice Act, then the physical therapist may provide the specific type of wound care services defined in the State Practice Act. Such visits in this specific situation can be billed as physical therapy visits and count toward the therapy threshold item in the case mix methodology.

EXAMPLE: A patient who is confined to the bed has developed a small-reddened area on the buttocks. The physician has ordered home health aide visits for more frequent repositioning, bathing and the application of a topical ointment and a gauze 4x4. Home health aide visits at an appropriate frequency would be reasonable and necessary.

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

NOTE: Prefilling of insulin syringes is ordinarily performed by the diabetic as part of the self-administration of the insulin and, unlike the injection of the insulin, does not require the skill of a licensed nurse to be performed properly. Therefore, if the prefilling of insulin syringes is performed by HHA staff, it is considered to be a home health aide service. However, where State law precludes the provision of this service by other than a licensed nurse or physician, Medicare will make payment for this service, when covered, as though it were a skilled nursing service. Where the patient needs only prefilling of insulin syringes and does not need skilled nursing care on an intermittent basis, physical therapy or speech-language pathology services or have a continuing need for occupational therapy, then Medicare cannot cover any home health services to the patient (even if State law requires that the insulin syringes be filled by a licensed nurse).

Home health aide services are those services ordered in the plan of care that the aide is permitted to perform under State law. Medicare coverage of the administration of insulin by a home health aide will depend on whether or not the agency is in compliance with all Federal and State laws and regulations related to this task. However, when the task of insulin administration has been delegated to the home health aide, the task must be considered and billed as a Medicare home health aide service. By a State allowing the delegation of insulin administration to home health aides, the State has extended the role of aides, not equated aide services with the services of a registered nurse.

d. 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.

e. Routine care of prosthetic and orthotic devices. When a home health aide visits a patient to provide a health related service as discussed above, the home health aide may also perform some incidental services that do not meet the definition of a home health aide service (e.g., light cleaning, preparation of a meal, taking out the trash, shopping). However, the purpose of a home health aide visit may not be to provide these incidental services since they are not health related services, but rather are necessary household tasks that must be performed by anyone to maintain a home.

EXAMPLE 1: A home health aide visits a recovering stroke patient whose right side weakness and poor endurance cause her to be able to leave the bed and chair only with extreme difficulty. The physician has ordered physical therapy and speech-language pathology services for the patient and has ordered home health aide services three or four times per week for personal care, assistance with ambulation as mobility increases, and assistance with repetitive speech exercises as her impaired speech improves. The home health aide also provides incidental household services such as preparation of meals, light cleaning and taking out the trash. The patient lives with an elderly frail sister who is disabled

and cannot perform either the personal care or the incidental tasks. The home health aide visits at a frequency appropriate to the performance of the health related services would be covered, notwithstanding the incidental provision of noncovered services (i.e., the household services) in the course of the visits.

EXAMPLE 2: A physician orders home health aide visits three times per week. The only services provided are light housecleaning, meal preparation and trash removal. The home health aide visits cannot be covered, notwithstanding their importance to the patient, because the services provided do not meet Medicare's definition of "home health aide services."

206.3 Medical Social Services.--Medical social services that are provided by a qualified medical social worker or a social work assistant under the supervision of a qualified medical social worker may be covered as home health services where the patient meets the qualifying criteria specified in §204, and:

- The services of these professionals are necessary to resolve social or emotional problems that are or are expected to be an impediment to the effective treatment of the patient's medical condition or his or her rate of recovery; and
- The plan of care indicates how the services that are required necessitate the skills of a qualified social worker or a social work assistant under the supervision of a qualified medical social worker to be performed safely and effectively.
- Where both of these requirements for coverage are met, services of these professionals that may be covered include, but are not limited to:
 - Assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment and adjustment to care;
 - Assessment of the relationship of the patient's medical and nursing requirements to the patient's home situation, financial resources and availability of community resources;
 - Appropriate action to obtain available community resources to assist in resolving the patient's problem. (Note: Medicare does not cover the services of a medical social worker to complete or assist in the completion of an application for Medicaid because Federal regulations require the State to provide assistance in completing the application to anyone who chooses to apply for Medicaid.);
- Counseling services which are required by the patient; and
- Medical social services furnished to the patient's family member or caregiver on a short-term basis when the HHA can demonstrate that a brief intervention (that is, two or three visits) by a medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the patient's medical condition or to his or her rate of recovery. 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. Medical social services to address general problems that do not clearly and directly impede treatment or recovery as well as long-term social services furnished to family members, such as ongoing alcohol counseling, are not covered.

NOTE: Participating in the development of the plan of care, preparing clinical and progress notes, participating in discharge planning and inservice programs, and acting as a consultant to other agency personnel are appropriate administrative costs to the HHA.

EXAMPLE 9: The parent of a dependent disabled child has been discharged from the hospital following a hip replacement. Although arrangements for care of the disabled child during the hospitalization were made, the child has returned to the home. During a visit to the patient, the nurse observes that the patient is transferring the child from bed to a wheelchair. In an effort to avoid impeding the patient's recovery, the nurse contacts the patient's physician to order a visit by a social worker to mobilize family members or otherwise arrange for temporary care of the disabled child.

206.4 Medical Supplies (Except for Drugs and Biologicals) and the Use of Durable Medical Equipment.--

A. Medical Supplies--Medical supplies are items that, due to their therapeutic or diagnostic characteristics, are essential in enabling HHA personnel to conduct home visits or to carry out effectively the care the physician has ordered for the treatment or diagnosis of the patient's illness or injury. All supplies which would have been covered under the cost-based reimbursement system are bundled under home health PPS. Payment for the cost of supplies has been incorporated into the per visit and episode payment rates. Supplies fit into two categories. They are classified as:

o Routine because they are used in small quantities for patients during the usual course of most home visits; or

o Nonroutine because they are needed to treat a patient's specific illness or injury in accordance with the physician's plan of care and meet further conditions discussed in more detail below.

All HHAs are expected to separately identify in their records the cost of medical and surgical supplies that are not routinely furnished in conjunction with patient care visits and the use of which are directly identifiable to an individual patient.

1. Routine Supplies (Non-Billable)--Routine supplies are supplies that are customarily used in small quantities during the course of most home care visits. They are usually included in the staff's supplies and not designated for a specific patient. These supplies are included in the cost per visit of home health care services. Routine supplies would not include those supplies that are specifically ordered by the physician or are essential to HHA personnel in order to effectuate the plan of care.

Examples of supplies which are usually considered routine include, but are not limited to:

- Dressings and Skin Care
Swabs, alcohol preps, and skin prep pads
Tape removal pads
Cotton balls
Adhesive and paper tape
Non-sterile applicators
4 x 4's
- Infection Control Protection
Non-sterile gloves
Aprons
Masks
Gowns

- Blood Drawing Supplies
Specimen containers

• Diapers and Chux Covered in the normal course of a visit. For example, if a home health aide in the course of a bathing visit requires a diaper change, the diaper in this example would be covered as a routine medical supply.

- Other
Thermometers
Tongue depressors

There are occasions when the supplies listed in the above examples would be considered nonroutine and thus would be considered a billable supply, i.e., if they are required in quantity, for recurring need, and are included in the plan of care. Examples include, but are not limited to, tape and 4x4's for major dressings.

2. Non-Routine Supplies (Billable).--Non-routine supplies are identified by the following conditions:

- The HHA follows a consistent charging practice for Medicare and non-Medicare patients receiving the item;

- The item is directly identifiable to an individual patient;

- The cost of the item can be identified and accumulated in a separate cost center;

and

- The item is furnished at the direction of the patient's physician and is specifically identified in the plan of care. The item is needed to treat a patient's specific illness or injury.

The charge for non-routine supplies is excluded from the per visit costs.

Examples of supplies which can be considered non-routine include, but are not limited to:

- Dressings/Wound Care
Sterile dressings
Sterile gauze and toppers
Kling and Kerlix rolls
Sterile solutions
Sterile applicators
Sterile gloves
- IV Supplies
- Ostomy Supplies
- Catheters and Catheter Supplies
Foley catheters
Drainage bags, irrigation trays

- Enemas and Douches
- Syringes and Needles

Consider other items that are often used by persons who are not ill or injured to be medical supplies only where (1) the item is recognized as having the capacity to serve a therapeutic or diagnostic purpose in a specific situation, and (2) the item is required as a part of the actual physician-prescribed treatment of a patient's existing illness or injury. For example, items that generally serve a routine hygienic purpose, e.g., soaps and shampoos and items that generally serve as skin conditioners, e.g., baby lotion, baby oil, skin softeners, powders, lotions, are not considered medical supplies unless the particular item is recognized as serving a specific therapeutic purpose in the physician's prescribed treatment of the patient's existing skin (scalp) disease or injury.

Limited amounts of medical supplies may be left in the home between visits where repeated applications are required and rendered by the patient or other caregivers. These items must be part of the plan of care in which the home health staff are actively involved. For example, the patient is independent in insulin injections but the nurse visits once a day to change wound dressings. The wound dressings/irrigation solution may be left in the home between visits. Do not leave supplies such as needles, syringes, and catheters that require administration by a nurse in the home between visits.

3. The Law, Routine and Non Routine Medical Supplies, and the Patient's Plan of Care.--
The Medicare law governing the home health PPS is specific to the type of items and services bundled to the HHA and the time the services are bundled. Medical supplies are bundled while the patient is under a home health plan of care. If a patient is admitted for a condition which is related to a chronic condition that requires a medical supply (e.g., ostomy patient) the HHA is required to provide the medical supply while the patient is under a home health plan of care during an open episode. The physician orders in the plan of care must reflect all non routine medical supplies provided and used while the patient is under a home health plan of care during an open 60 day episode. The consolidated billing requirement is not superseded by the exclusion of certain medical supplies from the plan of care and then distinguishing between medical supplies that are related and unrelated to the plan of care. Failure to include medical supplies on the plan of care does not relieve HHAs from the obligation to comply with the consolidated billing requirements. The comprehensive nature of the current patient assessment and plan of care requirements looks at the totality of patient needs. However, we could envision a circumstance where a physician could be uncomfortable with writing orders for a pre-existing condition unrelated to the reason for home health care. In those circumstances, PRN orders for such supplies may be used in the plan of care by a physician.

Thus, all medical supplies are bundled while the patient is under a home health plan of care during an open 60 day episode. This includes, but is not limited to, the above listed medical supplies as well as the Part B items provided in the final PPS rule. The latter item lists are subsequently updated in accordance with the current process governing the deletion, replacement and revision of Medicare Part B codes. Parenteral and enteral nutrition, prosthetics, orthotics, DME and DME supplies are not considered medical supplies and therefore not subject to bundling while the patient is under a home health plan of care during an open episode. However, §1834(h)(4)(c) of the Act specifically excludes from the term "orthotics and prosthetics" medical supplies including catheters, catheter supplies, ostomy bags and supplies related to ostomy care furnished by an HHA under §1861(m) of the Act. Therefore, these items are bundled while a patient is under a home health plan of care.

4. Relationship Between Patient Choice and Veterans Benefits.--For veterans, both Medicare and Veteran's Administration (VA) Benefits are primary. So the beneficiary who is a veteran has some choices in cases where the benefits overlap. An HHA must provide the medical supplies a patient needs; it is not obligated to provide medical supplies that a patient doesn't need. If a patient has medical supplies provided by the VA because of the patient's preference, then the HHA is not required to duplicate medical supplies. The beneficiary's choice is controlling. The HHA may not require the beneficiary to obtain or use medical supplies from any other source, including the VA.

5. Medical Supplies Purchased By the Patient Prior to the Start of Care.--A patient may have acquired medical supplies prior to his/her Medicare home health start of care date. If a patient prefers to use his or her own medical supplies after having been offered appropriate supplies by the HHA and it is determined by the HHA that the patient's medical supplies are clinically appropriate, then the patient's choice is controlling. The HHA is not required to duplicate the medical supplies if the patient elects to use his or her own medical supplies. However, if the patient prefers to have the HHA provide medical supplies while the patient is under a Medicare home health plan of care during an open episode, then the HHA must provide the medical supplies. The HHA may not require that the patient obtain or use medical supplies from any other source. Given the possibility of subsequent misunderstandings arising between the HHA and the patient on this issue, the HHA should document the beneficiary's decision to decline HHA furnished medical supplies and use their own resources.

B. Durable Medical Equipment.--Durable medical equipment which meets the requirements of §220 is covered under the home health benefit, with the beneficiary responsible for payment of a 20 percent coinsurance.

206.5 Services of Interns and Residents.--Home health services include the medical services of interns and residents-in-training under an approved hospital teaching program if the services are ordered by the physician who is responsible for the plan of care and the HHA is affiliated with or is under common control of a hospital furnishing the medical services. Approved means:

- A. Approved by the Accreditation Council for Graduate Medical Education;
- B. In the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;
- C. 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
- D. In the case of an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Education of the American Podiatric Association.

206.6 Outpatient Services.--Outpatient services include any of the items or services described above that are provided under arrangements on an outpatient basis at a hospital, skilled nursing facility (SNF), or rehabilitation center, and that (1) require equipment not readily available at the patient's place of residence, or (2) are furnished while the patient is at the facility to receive services. The hospital or SNF must be qualified providers of services. See §200.3 for special provisions for the use of the facilities of rehabilitation centers. The cost of transporting a patient to a facility cannot be paid.

206.7 Part-time or Intermittent Home Health Aide and Skilled Nursing Services.--Where a patient is eligible for coverage of home health services, Medicare covers either part-time or intermittent home health aide services and skilled nursing services subject to the limits below. The Balanced Budget Act of 1997 provided a statutory definition for the coverage of part-time or intermittent skilled nursing and home health aide services. The law at §1861(m) of the Act states: "the term "part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours each week).

A. Impact on Care Provided in Excess of "Intermittent" or "Part-time" Care.--Home health aide and/or skilled nursing care in excess of the amounts of care that meet these definitions of part-time or intermittent may be provided to a home care patient or purchased by other payers without bearing on whether the home health aide and skilled nursing care meets the Medicare definitions of part-time or intermittent.

EXAMPLE: A patient needs skilled nursing care monthly for a catheter change and the HHA also renders needed daily home health aide services 24 hours per day that will be needed for a long and indefinite period of time. The HHA bills Medicare for the skilled nursing and home health aide services that were provided before the 35th hour of service each week and bills the patient (or another payer) for the remainder of the care. If the intermediary determines that the 35 hours of care are reasonable and necessary, Medicare would cover the 35 hours of skilled nursing and home health aide visits.

D. Application of This Policy Revision--A patient must meet the longstanding and unchanged qualifying criteria for Medicare coverage of home health services, before this policy revision becomes applicable to skilled nursing services and/or home health aide services. The definition of "intermittent" with respect to the need for skilled nursing care where the patient qualifies for coverage based on the need for "skilled nursing care on an intermittent basis" remains unchanged. Specifically:

- This policy revision always applies to home health aide services when the patient qualifies for coverage;
- This policy revision applies to skilled nursing care only when the patient needs physical therapy, speech-language pathology services, or continued occupational therapy and also needs skilled nursing care; and
- If the patient needs skilled nursing care but does not need physical therapy, speech-language pathology services, or occupational therapy, the patient must still meet the longstanding and unchanged definition of "intermittent" skilled nursing care in order to qualify for coverage of any home health services.

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212. SPECIAL CONDITIONS FOR COVERAGE AND PAYMENT OF HOME HEALTH SERVICES UNDER HOSPITAL INSURANCE (PART A) AND SUPPLEMENTARY MEDICAL INSURANCE (PART B)--

212.1 Post-Institutional Home Health Services Furnished During A Home Health Spell Of Illness -Beneficiaries Enrolled In Part A and Part B.--Section 4611 of the BBA of 1997 revised the Part A home health benefit to gradually transfer from Part A to Part B the cost of Medicare home health services following a beneficiary's 3 consecutive day stay in a hospital or skilled nursing facility for a total of 100 visits in a home health spell of illness. Section 1812(a)(3) of the Act was amended by §4611 (a) of the BBA to provide post-institutional home health services for individuals enrolled in Part A and Part B and home health services for individuals who are eligible for Part A only. For beneficiaries who are enrolled in Part A and Part B, Part A finances post-institutional home health services furnished during a home health spell of illness for up to 100 visits during a spell of illness. Payment under Part A for post-institutional home health services furnished to an individual during a home health spell of illness may not be made for such services beginning after such services have been furnished for a total of 100 visits during such spell.

Section 1861(tt) of the Act, as added by §4611(b) of the BBA of 1997, defines "post-institutional home health services" and "home health spell of illness." Section 1861(tt)(1) of the Act defines "post-institutional home health services" as home health services furnished to an individual--(A) after discharge from a hospital or rural primary care hospital in which the individual was an inpatient for not less than 3 consecutive days before such discharge if such home health services were initiated within 14 days after the date of such discharge; or (B) after discharge from a skilled nursing facility in which the individual was provided post-hospital extended care services (i.e., covered Part A skilled nursing facility services following a qualifying hospital stay of at least 3 days) if such home health services were initiated within 14 days after the date of such discharge.

Section 1861(tt)(2) of the Act defines the term "home health spell of illness" with respect to any individual as a period of consecutive days--(A) beginning with the first day (not included in a previous home health spell of illness) (i) on which such individual is furnished post-institutional home health services, and (ii) which occurs in a month for which the individual is entitled to benefits under part A, and (B) ending with the close of the first period of 60 consecutive days thereafter on each of which the individual is neither an inpatient of a hospital or rural primary care hospital nor an inpatient of a facility described in §1819(a)(1) of the Act or subsection 1861(y)(1) of the Act nor provided home health services.

212.2 Beneficiaries Enrolled in Parts A and B and Meet the Institutional Care Threshold.--Part A finances up to 100 visits furnished during a home health spell of illness if the following criteria are met:

- Beneficiaries are enrolled in Part A **and** Part B and qualify to receive the Medicare home health benefit;
- Beneficiaries must have at least a 3 consecutive day stay in a hospital or rural primary care hospital; and
- Home health services must be initiated and the first covered home health visit must be rendered within 14 days of discharge from a 3 consecutive day stay in a hospital or rural primary care hospital or within 14 days of discharge from a skilled nursing facility in which the individual was provided post-hospital extended care services. If the first home health visit is not initiated within 14 days of discharge, then home health services are financed under Part B.

After an individual exhausts 100 visits of Part A post-institutional home health services, Part B finances the balance of the home health spell of illness. A home health spell of illness is a period of consecutive days beginning with the first day not included in a previous home health spell of illness on which the individual is furnished post-institutional home health services which occurs in a month the individual is entitled to Part A. The home health spell of illness ends with the close of the first period of 60 consecutive days in which the individual is neither an inpatient of a hospital or rural primary care hospital nor an inpatient of a skilled nursing facility (in which the individual was furnished post-hospital extended care services) nor provided home health services.

212.3 Beneficiaries Who Are Enrolled In Part A and Part B, But Do Not Meet Threshold For Post-Institutional Home Health Services.--If beneficiaries are enrolled in Part A and Part B and are eligible for the Medicare home health benefit, but do not meet the 3 consecutive day stay requirement or the 14 day initiation of care requirement, then all of their home health services would be financed under Part B. For example, this situation would include, but is not limited to, beneficiaries enrolled in Part A and Part B who are coming from the community to a home health agency in need of home health services or who stay less than 3 consecutive days in a hospital and are discharged. Any home health services received after discharge would be financed under Part B.

212.4 Beneficiaries Who Are Part A Only Or Part B Only.--If a beneficiary is enrolled **only** in Part A and qualifies for the Medicare home health benefit, then all of the home health services are financed under Part A. The 100-visit limit does **not** apply to beneficiaries who are only enrolled in Part A. If a beneficiary is enrolled **only** in Part B and qualifies for the Medicare home health benefit, then all of the home health services are financed under Part B. There is no 100 visit limit under Part B. The new definition of post-institutional home health services provided during a home health spell of illness **only** applies to those beneficiaries who are enrolled in **both** Part A and Part B and qualify for the Medicare home health benefit.

212.5 Coinsurance, Copayments, and Deductibles.--Section 4611 of the BBA of 1997 did **not** change the current treatment of coinsurance, copayments, or deductibles for home health services. There is no coinsurance, copay or deductible for home health services and supplies other than the coinsurance required for durable medical equipment covered as a home health service. The coinsurance liability of the beneficiary for durable medical equipment furnished as a home health service is 20 percent of the customary (insofar as reasonable) charge for the services.

215. DURATION OF HOME HEALTH SERVICES

215.1 Number of Home Health Visits Under Hospital Insurance (Part A).--To the extent that all coverage requirements are met, payment may be made on behalf of eligible beneficiaries under Part A for an unlimited number of covered home health visits. **The determination of Part A or Part B Trust fund financing and coverage is made in accordance with the financing shift required by the BBA described above in §212.** All Medicare home health services are covered under Part A unless there is no Part A entitlement.

215.2 Number of Home Health Visits Under Supplementary Medical Insurance (Part B).--To the extent that all coverage requirements are met, payment may be made on behalf of eligible beneficiaries under Part B for an unlimited number of covered home health visits. **The determination of Part A or Part B Trust fund financing and coverage is made in accordance with the financing shift required by the BBA described above in §212 .**

218. COUNTING VISITS UNDER THE HOSPITAL AND MEDICAL PLANS

The number of visits are counted in the same manner under both the hospital plan and medical plan.

218.1 Visit Defined.--A visit is an episode of personal contact with the patient by staff of the HHA, or others under arrangements with the HHA, for the purpose of providing a covered home health service.

218.2 Counting Visits.--Generally, one visit may be covered each time an HHA employee, or someone providing home health services under arrangements with the HHA, enters the patient's home and provides a covered service to a patient who meets the criteria in §204.

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.

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.

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 patient's home between visits (e.g., 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.

EXAMPLE 1: If an occupational therapist and an occupational therapy assistant visit the patient together to provide therapy and the therapist is there to supervise the assistant, one visit is covered.

EXAMPLE 2: If a nurse visits the patient in the morning to dress a wound and later must return to replace a catheter, two visits are covered.

EXAMPLE 3: If the therapist visits the patient for treatment in the morning and the patient is later visited by the assistant for additional treatment, two visits are covered.

EXAMPLE 4: If a patient is taken to a hospital to receive outpatient therapy that could not be furnished in his/her own home (e.g., hydrotherapy) and, while at the hospital receives speech-language pathology and other services, two or more visits would be covered.

EXAMPLE 5: Although many HHAs provide home health aide services on an hourly basis (ranging from 1 to 8 hours a day), home health aide services are covered in terms of visits. Thus, regardless of the number of continuous hours a home health aide spends in a patient's home **to provide continuous covered care** on any given day, one "visit" is covered for each such day. If, in a rare situation, a home health aide visits a patient for an hour or two in the morning, and again for an hour or two in the afternoon, two visits would be covered.

218.3 Evaluation Visits.--HHAs are required by regulations to have written policies concerning the acceptance of patients by the agency. These include consideration of the physical facilities available in the patient's place of residence, the homebound status, and the attitudes of family members for the purpose of evaluating the feasibility of meeting the patient's medical needs in the home health setting. When personnel of the agency make such an initial evaluation visit, the cost of the visit is considered an administrative cost of the agency and is not chargeable as a visit since at this point the patient has not been accepted for care. If, however, during the course of this initial evaluation visit, the patient is determined suitable for home health care by the agency, and is also furnished the first skilled service as ordered under the physician's plan of treatment, the visit would become the first billable visit **in the 60 day episode**.

An observation and evaluation (or reevaluation) visit made by a nurse (see §204.4 for a further discussion of skilled nursing observation and evaluation visits) or other appropriate personnel, ordered by the physician for the purpose of evaluating the patient's condition and his or her continuing need for skilled services, would be covered as a skilled visit.

A supervisory visit made by a nurse or other appropriate personnel (as required by the conditions of participation) to evaluate the specific personal care needs of the patient or to review the manner in which the personal care needs of the patient are being met by the aide is considered an administrative function and is not chargeable to the patient as a skilled visit.

219. MEDICAL AND OTHER HEALTH SERVICES

The voluntary medical insurance plan (Part B) is designed to supplement the basic hospital insurance (Part A) coverage. In addition to providing coverage for unlimited home health visits in a calendar year (see §215.2), the medical insurance plan provides coverage for certain "medical and other health services." Reimbursement may be made to a home health agency (HHA) that furnishes either directly or under arrangements with others the following "medical and other health services" to beneficiaries with Part B coverage **in accordance with Part B billing rules.**

- Surgical dressings (**for a patient who is not under a home health plan of care**), and splints, casts, and other devices used for reduction of fractures and dislocations. (See §219.1.)
- Prosthetic devices. (See §219.2.) (**Except for items excluded from the term "orthotics and prosthetics" in accordance with §1834(h)(4)(C) of the Act for patients who are under a home health plan of care**)
 - Leg, arm, back, and neck braces, trusses, and artificial legs, arms and eyes. (See §219.3.)
 - Outpatient physical therapy, outpatient occupational therapy, and outpatient speech-language pathology services (**for a patient not under a home health plan of care**). (See §219.4.)
 - Rental and purchase of durable medical equipment. (See §§220ff.) Effective July 18, 1984, the coverage of durable medical equipment (DME) is substituted for the coverage of medical appliances under the home health benefit. Where a beneficiary meets all of the criteria for coverage of home health services and the home health agency (HHA) is providing the home health care under the Hospital Insurance Program (Part A), any DME provided by the HHA to that patient must also be provided under Part A. Where the patient meets the criteria for coverage of home health services and the HHA is providing the home health care under the Supplementary Medical Insurance Program (Part B) because the patient is not eligible for Part A, the DME provided by the HHA may, at the beneficiary's option, be furnished under the Part B home health benefit or as a medical and other health service. Irrespective of how the DME is furnished, the beneficiary is responsible for a 20 percent coinsurance.
 - Ambulance service. (See §221.)
 - Hepatitis B Vaccine. Vaccinations or inoculations are excluded from coverage as "immunizations" unless they are directly related to the treatment of an injury or direct exposure to a disease or condition. An exception was made in 1980 to include coverage of pneumococcal vaccinations.

With the enactment of the Deficit Reduction Act of 1984 (P.L. 98-369), coverage under Part B is extended to hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. This coverage is effective for services furnished on or after September 1, 1984.

High-risk groups currently identified include:

End-Stage Renal Disease (ESRD) patients;
Hemophiliacs who receive Factor VIII or IX concentrates;
Clients of institutions for the mentally retarded;
Persons who live in the same household as an Hepatitis B Virus (HBV) carrier;
Homosexual men;
Illicit injectable drug abusers.

Intermediate risk groups currently identified include:

Staff in institutions for the mentally retarded;
Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

Exception:

Persons in the above-listed groups would not be considered at high or intermediate risk of contracting hepatitis B, however, if there is laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For Medicare program purposes, the vaccine may be administered--upon the order of a doctor of medicine or osteopathy--by home health agencies, skilled nursing facilities,

ESRD facilities, hospital outpatient departments, persons recognized under the incident to physicians' services provision of the law, and, of course, doctors of medicine and osteopathy.

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

- Hemophilia clotting factors. Blood clotting factors for hemophilia patients competent to use such factors to control bleeding without medical or other supervision and items related to the administration of such factors are covered under Part B. Coverage is effective for such items and services purchased on or after July 18, 1984. Prior to the enactment of the Deficit Reduction Act of 1984 (P.L. 98-369), all drugs and biologicals which were of the type that could be self-administered were excluded from coverage. The coverage of blood clotting factors is an exception to the exclusion.

The amount of clotting factors determined to be necessary to have on hand and thus covered under this provision is based on the historical utilization pattern or profile developed by the carrier for each patient. The treating source (e.g., a family physician or comprehensive hemophilia diagnostic and treatment center) must have such information. From this data, the contractor must be able to make reasonable projections concerning the quantity of clotting factors anticipated to be needed by the patient over a specific period of time. Unanticipated occurrences involving extraordinary events, such as automobile accidents, inpatient hospital stays, etc., change this base line data and must be appropriately considered. In addition, changes in a patient's medical needs over a period of time require adjustments in the profile.

219.1 Surgical Dressings, and Other Dressings Used for Reduction of Fractures and Dislocations.--Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional to the extent permissible under State law. In addition, surgical dressings required after debridement of a wound are also covered, irrespective of the type of debridement, as long as the debridement was reasonable and necessary and was performed by a health care professional who was acting within the scope of his or her legal authority when performing this function. Surgical dressings are covered for as long as they are medically necessary.

Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. Items such as adhesive tape, roll gauze, bandages, and disposable compression material are examples of secondary dressings. Elastic stockings, support hose, foot coverings, leotards, knee supports, surgical leggings, gauntlets and pressure garments for the arms and hands are examples of items that are not ordinarily covered as surgical dressings. Some items, such as transparent film, may be used as a primary or secondary dressing.

If a physician, certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner. When surgical dressings are not covered incident to the services of a health care practitioner and are obtained by the patient from an HHA on an order from a physician or other health care professional **authorized under State law or regulation to make such an order while the patient is under a home health plan of care during an open 60 day episode, the surgical dressings and other related medical supplies that meet the definition of a medical supply under the Medicare home health benefit are subject to the consolidated billing requirements governing home health PPS described in §201.**

219.2 Prosthetic Devices.--Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ and replacements or repairs of such **devices are covered when furnished incident to physicians' services or on a physician's orders. Part B coverage is provided except for items excluded from the term "orthotics and prosthetics" in accordance with §1834(h)(4)(C) of the Act for patients who are under a home health plan of care. Those prosthetics that are covered as medical supplies under the home health benefit, are bundled into the episode payment and subject to the consolidated billing requirements while a patient is under a home health plan of care.**

Colostomy (and other ostomy) bags and necessary accoutrements required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care whether or not the attachment of a bag is required.

Examples of prosthetic devices include cardiac pacemakers, hemodialysis equipment (see §220.1B1), prosthetic lenses, breast prostheses (including a surgical brassiere) for postmastectomy patients, maxillofacial devices and devices which replace all or part of the function of the ear or nose. A urinary collection and retention system with or without a tube would be a prosthetic device replacing bladder function in cases of permanent urinary incontinence. The Foley catheter would also be considered a prosthetic device when ordered for a patient with permanent urinary incontinence. However, chux, diapers, rubber sheets, etc., are not covered under this provision since they do not perform the collecting and retention function of the bladder.

Total parenteral nutrition (TPN) systems and enteral nutrition (EN) systems are covered by Medicare as prosthetic devices when the criteria in HHA-3 of the Coverage Issues Manual are met. When these criteria are met, the equipment and supplies which (together with nutrients) compose the prosthetic device are not considered to be durable medical equipment and medical supplies and therefore may not be covered as home health services. When a home health agency supplies TPN or EN systems which meet the criteria for coverage as a prosthetic device, bill the carrier designated to process claims for TPN and EN systems. (See §403.)

219.3 Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes.--These appliances are covered under Part B when furnished incident to physicians' services or on a physician's order. A brace includes rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Back braces include, but are not limited to, special corsets, sacroiliac, sacrolumbar, dorsolumbar corsets and belts. A terminal device (e.g., hand or hook) is covered under this provision whether or not an artificial limb is required by the patient.

Stump stockings and harnesses (including replacements) are also covered when these appliances are essential to the effective use of the artificial limb.

Adjustments to an artificial limb or other appliance required by wear or by a change in the patient's condition are covered when ordered by a physician. To the extent applicable the provisions relating to the repair and replacement of durable medical equipment (see §220.4) should be followed with respect to the repair and replacement of artificial limbs, braces, etc. Adjustments, repairs, and replacement are covered even when the item had been in use before the user enrolled in Part B of the program so long as the device continues to be medically required.

219.4 Outpatient Physical Therapy, Occupational Therapy, and Speech Pathology Services.--Physical therapy, occupational therapy, and speech pathology services provided to outpatients by a participating hospital, skilled nursing facility, home health agency, clinic, rehabilitation agency or public health agency or by others under arrangements with and under the supervision of such an institution or agency are covered as "medical and other health services" under Part B of the program.

NOTE: An individual is not required to be homebound or meet any other Medicare home health eligibility requirements in order to be eligible for these benefits as they are not under a home health plan of care. However, if an individual is under a home health plan of care during an open episode and is receiving the therapies under arrangement on behalf of the HHA, these services are subject to the consolidated billing requirements governing home health PPS described in §201.)

To be covered under the "medical and other health services" provision, outpatient physical therapy, occupational therapy, or speech pathology services must meet all of the conditions set forth in §§205.1, 205.2, or 205.3, respectively. In addition, outpatient physical therapy, occupational therapy, or speech pathology services must meet all of the following conditions.

A. Content of the Physician's Certification.--No payment may be made for outpatient physical therapy, occupational therapy, or speech pathology services unless a physician certifies that:

1. the services are or were furnished while the patient was under the care of a physician (see D);
2. a plan for furnishing such services is or was established by the physician, physical therapist, occupational therapist or speech pathologist and periodically reviewed by the physician (See E); and

3. the services are or were required by the patient.

Since the certification is closely associated with the plan of treatment, the same physician who establishes or reviews the plan must certify to the necessity for the services. Obtain certification at the time the plan of treatment is established or as soon thereafter as possible. "Physician" means a doctor of medicine, a doctor of osteopathy (including an osteopathic practitioner), or a doctor of podiatric medicine legally authorized to practice by the State in which he performs the services. In addition, physician certification by doctors of podiatric medicine must be consistent with:

- the scope of the professional services provided by a doctor of podiatric medicine as authorized by applicable State law and
- the policy of the agency with respect to which the services are performed.

B. Recertification.--When outpatient physical therapy, occupational therapy, or speech pathology services are continued under the same plan of treatment for a period of time, the physician must recertify at intervals of at least once every 30 days that there is a continuing need for such services and should estimate how long services will be needed. The recertification should be obtained at the time the plan of treatment is reviewed since the same interval (at least once every 30 days) is required for the review of the plan. Recertifications must be signed by the physician who reviews the plan of treatment. The form of the recertification and the manner of obtaining timely recertification is up to the home health agency.

For information regarding the method and disposition of certifications (see §240.2), and for delayed certification (see §240.4).

C. Outpatient.--Outpatient physical therapy, occupational therapy, and speech pathology services are covered when furnished by a provider to its outpatients, i.e., to patients in their homes, to patients who come to the facility's outpatient department, or to inpatients of other institutions. In addition, coverage includes physical therapy, occupational therapy, and speech pathology services furnished by participating hospitals and skilled nursing facilities to those of their inpatients who have exhausted their Part A inpatient benefits or who are otherwise not eligible for Part A benefits. Providers of outpatient physical therapy, occupational therapy, and speech pathology services that have inpatient facilities, other than participating hospitals and skilled nursing facilities, may not furnish covered outpatient physical therapy, occupational therapy, or speech pathology services to their own inpatients. However, since the inpatients of one institution may be considered the outpatients of another institution, all providers of outpatient physical therapy, occupational therapy, and speech pathology services may furnish such services to inpatients of another health facility. **Due to the consolidated billing requirements in the law governing home health PPS, if a patient is under a home health plan of care and receives outpatient physical therapy, occupational therapy, or speech pathology services under arrangement on behalf of the HHA, the payment for those services is bundled to the HHA while the patient is under an open episode.**

While outpatient physical therapy, occupational therapy, and speech pathology services are payable when furnished in the home, when added expense is caused by a visit to the home, a question must be raised as to whether the rendition of the service in the home is reasonable and necessary. Where the patient is not confined to his home, such added expense cannot be considered as reasonable and necessary for the treatment of an illness or injury since the home visit is more costly than the medically appropriate and realistically feasible alternative pattern of care; e.g., in the facility's outpatient department. Consequently, these additional expenses incurred by providers due to travel to a person who is not homebound are not covered.

D. Outpatient Must Be Under the Care of a Physician.--Outpatient physical therapy, occupational therapy, or speech pathology services must be furnished to an individual who is under the care of a physician. There must be evidence in the patient's clinical record that a physician has seen him at least every 30 days. If the record does not reflect this, the provider is responsible for contacting the physician to determine whether this requirement is met. The physician may be the patient's private physician, a physician on the staff of the provider, a physician associated with an institution which is the patient's residence, or a physician associated with a medical facility in which the patient is an inpatient. The attending physician establishes or reviews the plan of treatment and also makes the necessary certifications.

E. Outpatient Physical Therapy, Occupational Therapy, or Speech Pathology Services Furnished Under a Plan.--Outpatient physical therapy, outpatient occupational therapy, or outpatient speech pathology services must be furnished under a written plan of treatment established by:

- a physician after any necessary consultation with the physical therapist, occupational therapist, or speech pathologist, as appropriate;
- the physical therapist who will provide the physical therapy services;
- the occupational therapist who will provide the occupational therapy services; or
- the speech pathologist who will provide the speech pathology services.

The plan must be established (that is, reduced to writing either by the person who established the plan or by the provider when it makes a written record of that person's oral orders) before treatment is begun. The plan should be promptly signed by the ordering physician, therapist, or pathologist and incorporated into the provider's permanent record for the patient.

The plan must relate the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech pathology services that are to be furnished the patient and indicate the diagnosis and anticipated goals. Any changes to this plan must be made in writing and signed by the physician, therapist, or pathologist. Changes to the plan may also be made pursuant to oral orders given by the attending physician to a qualified physical therapist (in the case of physical therapy services), a qualified occupational therapist (in the case of occupational therapy services), a qualified speech pathologist (in the case of speech pathology services), a registered professional nurse, or a physician on the staff of the provider.

Changes to such plans also may be made pursuant to oral orders given by the pathologist to another qualified speech pathologist, by the occupational therapist to another qualified occupational therapist, or by the physical therapist to another qualified physical therapist, or by the therapist or pathologist to a registered professional nurse on the staff of the provider. Such changes must be immediately recorded in the patient's records and signed by the individual receiving the orders. While the physician may change a plan of treatment established by the pathologist or therapist providing such services, the therapist or pathologist may not alter a plan of treatment established by a physician.

The plan must be reviewed by the attending physician, in consultation with the HHA's physical therapist(s), occupational therapist(s), or speech pathologist(s) at such intervals as the severity of the patient's condition requires, but at least every 30 days. Each review of the plan should contain the initials of the physician and the date performed. The patient's plan normally need not be forwarded to the intermediary for review but will be retained in the agency's file. The HHA must certify on the billing form that the plan is on file. (See §§401ff.)

220. RENTAL AND PURCHASE OF DURABLE MEDICAL EQUIPMENT

A participating provider of service may be reimbursed under Part B on a reasonable cost basis for durable medical equipment which it rents or sells to a beneficiary for use in his home if the following three requirements are met:

- The equipment meets the definition of durable medical equipment (§220.1); and
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his malformed body member (§220.2); and
- The equipment is used in the patient's home (§220.3).

Payment may also be made under this provision for repairs, maintenance, and delivery of equipment as well as for expendable and nonreusable items essential to the effective use of the equipment subject to the conditions in §220.4.