CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10438	**Date: November 6, 2020**
	Change Request 12023

SUBJECT: Home Health Manual Update to Incorporate Allowed Practitioners into Home Health Policy

I. SUMMARY OF CHANGES: This Change Request (CR) updates the Medicare Benefit Policy Manual, Publication 100-02, Chapter 7. In accordance with section 3708(f) of the CARES Act, CMS amended the regulations to define a Nurse Practitioner (NP), a Clinical Nurse Specialist (CNS), and a Physician Assistant (PA) as "allowed practitioners." This means that in addition to a physician, an "allowed practitioner" may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare Home Health (HH) benefit. Additionally, CMS amended the regulations to reflect that CMS would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed NP in an acute or post-acute facility from which the patient was directly admitted to HH, the certifying practitioner may be different from the provider performing the face-to-face encounter.

EFFECTIVE DATE: March 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 11, 2021
Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	7/Table of Contents
R	7/10/10.1/National 30-Day Period Payment Rate
R	7/10/10.5/Physician and Allowed Practitioner Signature Requirements for the Split Percentage Payments
R	7/10/10.7/Partial Payment Adjustment
R	7/10/10.10/Consolidated Billing
R	7/20/20.1.1/Background
R	7/30/Conditions Patient Must Meet to Qualify for Coverage of Home Health Services
R	7/30/30.1.1/Patient Confined to the Home
R	7/30/30.2/Services Are Provided Under a Plan of Care Established and Approved by a Physician or Allowed Practitioner
N	7/30/30.2.1/Definition of Allowed Practitioner
R	7/30/30.2.2/Content of the Plan of Care
R	7/30/30.2.3/Specificity of Orders
R	7/30/30.2.4/Who Signs the Plan of Care
R	7/30/30.2.5/Timeliness of Signature
R	7/30/30.2.6/Use of Oral (Verbal) Orders
R	7/30/30.2.7/Frequency of Review of the Plan of Care
R	7/30/30.2.8/Facsimile Signatures
R	7/30/30.2.9/Alternative Signatures
R	7/30/30.2.10/Termination of the Plan of Care - Qualifying Services
R	7/30/30.2.11/Sequence of Qualifying Services and Other Medicare Covered Home Health Services
R	7/30/30.3/Under the Care of a Physician or Allowed Practitioner
R	7/30/30.4/Needs 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 Has Continued Need for Occupational Therapy
R	7/30/30.5/Physician or Allowed Practitioner Certification and Recertification of Patient Eligibility for Medicare Home Health Services
R	7/30/30.5.1/Physician or Allowed Practitioner Certification
R	7/30/30.5.1.1/Face-to-Face Encounter
R	7/30/30.5.1.2/Supporting Documentation Requirements

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	7/30/30.5.2/Physician or Allowed Practitioner Recertification
R	7/30/30.5.3/Who May Sign the Certification or Recertification
R	7/30/30.5.4/Physician or Allowed Practitioner Billing for Certification and Recertification
R	7/40 - Covered Services Under a Qualifying Home Health Plan of Care
R	7/40/40.1.1/General Principles Governing Reasonable and Necessary Skilled Nursing Care
R	7/40/40.1.2.8/Wound Care
R	7/40/40.1.2.10/Heat Treatments
R	7/40/40.1.2.13/Venipuncture
R	7/40/40.1.2.15/Psychiatric Evaluation, Therapy, and Teaching
R	7/40/40.1.3/Intermittent Skilled Nursing Care
R	7/40/40.2.1/General Principles Governing Reasonable and Necessary Physical
R	7/50/50.2/Home Health Aide Services
R	7/50/50.4.1/Medical Supplies
R	7/50/50.4.1.1/The Law, Routine and Nonroutine Medical Supplies, and the Patient's Plan of Care
R	7/50/50.4.1.2/Routine Supplies (Nonreportable)
R	7/50/50.4.1.3/Nonroutine Supplies (Reportable)
R	7/50/50.4.3/Covered Osteoporosis Drugs
R	7/50/50.5/Services of Interns and Residents
R	7/70/70.2/Counting Visits Under the Hospital and Medical Plans
R	7/80/80.10/Telecommunications Technology
R	7/90/Medical and Other Health Services Furnished by Home Health Agencies
R	7/100/Physician or Allowed Practitioner Certification for Medical and Other Health Services Furnished by Home Health Agency (HHA)
R	7/110/Use of Telehealth in Delivery of Home Health Services

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 10438	Date: November 6, 2020	Change Request: 12023

SUBJECT: Home Health Manual Update to Incorporate Allowed Practitioners into Home Health Policy

EFFECTIVE DATE: March 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 11, 2021

I. GENERAL INFORMATION

A. Background: Section 3708 of the CARES Act amended sections 1814(a) and 1835(a) of the Act to allow NPs, CNSs, and PAs (as those terms are defined in section 1861(aa) of the Act), to order and certify patients for eligibility under the Medicare HH benefit. Additionally, section 3708 of the CARES Act amended sections 1814(a)(2)(C), 1835 (a)(2)(A)(ii), and 1861(m) of the Act to allow the HH plan of care to be established and periodically reviewed by a physician, NPs, CNS, or PAs where such services are or were furnished while the individual was under the care of a physician, NP, CNS, or PA. The CARES Act also amended sections 1861(o)(2) and 1861(kk) of the Act to allow certified-nurse midwives (CNMs), NPs, CNSs, or PAs to perform the role originally reserved for a physician in establishing Home Health Agency (HHA) policies that govern the services (and supervision of such services) provided to patients under the Medicare HH benefit, as well as certify that an individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer the osteoporosis drug or is otherwise mentally or physically incapable of self-administering such drug. Finally, section 3708 of the CARES Act amended section 1895(c) of the Act to allow payment for the furnishing of items and services under the Home Health Prospective Payment System (HH PPS) when these items and services are prescribed by an NP, CNS, or PA. In accordance with section 3708 of the CARES Act, these changes are required to take effect within 6 months of enactment of the law and the Secretary shall issue an Interim Final Rule with Comment Period (IFC), if necessary to comply with the required effective date.

B. Policy: In accordance with section 3708(f) of the CARES Act, CMS amended the regulations at parts 409, 424, and 484 to define a NP, a CNS, and a PA (as such qualifications are defined at §§ 410.74 through 410.76) as an "allowed practitioner". This means that in addition to a physician, as defined at section 1861(r) of the Act, an "allowed practitioner" may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare HH benefit. Additionally, CMS amended the regulations to reflect that CMS would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed NP, as set out at 42 CFR 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to HH, the certifying practitioner may be different from the provider performing the face-to-face encounter. CMS implemented these changes in the regulations in the IFC: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program. Effective on March 1, 2020, NPs, CNSs, and PAs are able to practice to the top of their state licensure to certify eligibility for HH services, as well as establish and periodically review the HH plan of care. In accordance with section 1861(aa)(5) of the Act, NPs, CNSs, and PAs are required to practice in accordance with state law in the state in which the individual performs such services, as individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12023.1	The contractors shall be aware of the revisions to Pub. 100-02, Chapter 7 related to the new policies in this CR.			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Amanda Barnes, 443-651-1207 or amanda.barnes@cms.hhs.gov, Kelly Vontran, 410-786-0332 or kelly.vontran@cms.hhs.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Benefit Policy Manual
Chapter 7 - Home Health Services

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(Rev. 10438, Issued: 11-06-20)

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10.1 - National 30-Day *Period Payment* Rate

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

10.5 – Physician *or Allowed Practitioner* Signature Requirements for the Split Percentage Payments

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

A. Initial Percentage Payment

If a physician *or allowed practitioner* signed plan of care is not available at the beginning of the 30-day period, the HHA may submit a RAP for the initial percentage payment based on verbal orders OR a referral prescribing detailed orders for the services to be rendered that is signed and dated by the physician *or allowed practitioner*. If the RAP submission is based on a *physician or allowed practitioner's* verbal orders, the verbal order must be recorded in the plan of care as required at §§484.60(b)(4) and 409.43(d). The plan of care is copied and immediately submitted to the physician *or allowed practitioner*. A billable visit must be rendered prior to the submission of a RAP.

The 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 30-day period of care 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 *or allowed practitioner* who meets the certification and recertification requirements of 42 CFR 424.22 before the claim for each 30-day period of care for services is submitted for the final percentage payment. Any changes in the plan of care must be signed and dated by a physician *or allowed practitioner*.

10.7 - Partial Payment Adjustment

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

A. Partial Payment Adjustment Criteria

An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines an intervening event warrants a new 30-day period for purposes of payment.

The partial payment adjustment is a proportion of the period payment and is based on the span of days including the start-of-care date (for example, the date of the first billable service) through and including the last billable service date under the original plan of care before the intervening event, defined as a—

- Beneficiary elected transfer, or
- *Discharge and return to home health that would warrant, for purposes of payment, a new OASIS assessment, certification of eligibility, and a new plan of care.*

When a new 30-day period begins due to an intervening event, the original 30-day period will be proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event. The proportional payment is the partial payment adjustment.

B. Methodology Used to Calculate Partial Payment Adjustment

The partial payment adjustment for the original 30-day period 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 partial payment adjustment will be calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of the 30-day period. The proportion will then be multiplied by the original case-mix and wage index to produce the 30-day payment.

C. Common Ownership Exception to Partial Payment Adjustment

The partial payment adjustment does not apply in situations of transfers among HHAs of common ownership. 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 30-day period. The common ownership exception to the transfer partial payment adjustment does not apply if the beneficiary moved out of their Metropolitan Statistical Area (MSA) or non-MSA during the 30-day period before the transfer to the receiving HHA.

D. 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 484.50(d). The receiving HHA must also document in the record that it accessed the Medicare contractor's inquiry system to determine whether or not the patient was under an established home health plan of care and it must contact the initial HHA on the effective date of transfer. In the rare circumstance of a dispute between HHAs, the Medicare contractor is responsible for working with both HHAs to resolve the dispute. If the receiving HHA can provide documentation of its notice of patient rights on Medicare payment liability provided to the patient upon transfer and its contact of the initial HHA of the transfer date, then the initial HHA will be ineligible for payment for the period of overlap in addition to the appropriate partial payment adjustment. If the receiving HHA cannot provide the appropriate documentation, the receiving HHA's RAP and/or final claim will be cancelled, and full period payment will be provided to the initial HHA. For the receiving HHA to properly document that it contacted the initial HHA on the effective date of transfer it must maintain similar information as the initial HHA, including the same basic beneficiary information, personnel contacted, dates and times. The initial HHA must also properly document that it was contacted and it accepted the transfer. Where it disputes a transfer, the initial HHA must call its Medicare contractor to resolve the dispute. The Medicare contractor is responsible for working with both HHAs to resolve the dispute.

10.10 - Consolidated Billing

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

For individuals under a home health plan of care, payment for all services and supplies, with the exception of certain injectable osteoporosis drugs, DME, and furnishing NPWT using a disposable device is included in the HH PPS base payment rates. HHAs must provide the covered home health services (except DME) either directly or under arrangement, and must bill for such covered home health services.

Payment must be made to the HHA.

A. Home Health Services Subject to Consolidated Billing Requirements

The home health services included in the consolidated billing governing the HH 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 nonroutine medical supplies;
- Covered osteoporosis drug as defined in §1861(kk) of the Act, but excluding other drugs and biologicals;
- Furnishing NPWT using a disposable device as that term is defined in §1834 of the Act, which includes the professional services (specified by the assigned CPT code) that are provided;
- 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) of the Act 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 that all medical supplies (routine and nonroutine) be provided by the HHA while the patient is under a home health plan of care. The agency that establishes the 30-day period is the only entity that can bill and receive payment for medical supplies during a 30-day period for a patient under a home health plan of care. Both routine and nonroutine 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 30-day period.

Due to the consolidated billing requirements, CMS provided additional amounts in the base rates for those nonroutine medical supplies that have a duplicate Part B code that could have been unbundled to Part B prior to HH PPS. See §50.4 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 into the HHA 30-day period 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 medical supplies.

DME, including supplies covered as DME, are paid separately from the HH PPS and are excluded from the consolidated billing requirements governing the HH PPS. The determining factor is the medical classification of the supply, not the diagnosis of the patient.

Certain injectable osteoporosis drugs are included in consolidated billing under the home health benefit. However, payment is not bundled into the HH PPS payment rates. HHAs must bill for the osteoporosis drug in accordance with billing instructions. Payment is in addition to the HH PPS payment.

Furnishing NPWT using a disposable device is included in consolidated billing under the home health benefit. However, payment is not bundled into the HH PPS payment rates. HHAs must bill for NPWT using a disposable device in accordance with billing instructions. Payment is in addition to the HH PPS payment.

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 HH 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 HH 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 paid under the physician fee schedule are not recognized as home health services included in the PPS rates. Supplies incident to a physician service or related to a physician service billed to the Medicare contractor are not subject to the consolidated billing requirements. The physician would not be acting as a supplier billing the DME Medicare contractor 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, CMS has included in the 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 Healthcare Common Procedure Coding System (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 and cannot be separately billed to Part B during an open 30-day period of care.

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 HH 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 30-day period. 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 *or allowed practitioner* 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 (unaware of physician *or allowed practitioner* orders) of the services provided by an entity during a 30-day period 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 a 30-day period 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 a 30-day period in an effort to resolve any misunderstanding and avoid such situations in the future.

20.1.1 - Background

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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

30 - Conditions Patient Must Meet to Qualify for Coverage of Home Health Services

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

To qualify for the Medicare home health benefit, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, a Medicare beneficiary must meet the following requirements:

- Be confined to the home;
- Under the care of a physician *or allowed practitioner*;
- Receiving services under a plan of care established and periodically reviewed by a physician *or allowed practitioner*;
- Be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or
- Have a continuing need for occupational therapy.

For purposes of benefit eligibility, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

A patient must meet each of the criteria specified in this section. Patients who meet each of these criteria are eligible to have payment made on their behalf for services discussed in §§40 and 50.

30.1.1 - Patient Confined to the Home

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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 *or allowed practitioner* certify in all cases that the patient is confined to his/her home. For purposes of the statute, an individual shall be considered “confined to the home” (homebound) if the following two criteria are met:

1. Criterion One:

The patient must either:

- Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence

OR

- Have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the criterion one conditions, then the patient must ALSO meet two additional requirements defined in criterion two below.

2. Criterion Two:

    - There must exist a normal inability to leave home;

    AND

    - Leaving home must require a considerable and taxing effort.

To clarify, in determining whether the patient meets criterion two of the homebound definition, the clinician needs to take into account the illness or injury for which the patient met criterion one and consider the illness or injury in the context of the patient's overall condition. The clinician is not required to include standardized phrases reflecting the patient's condition (e.g., repeating the words "taxing effort to leave the home") in the patient's chart, nor are such phrases sufficient, by themselves, to demonstrate that criterion two has been met. For example, longitudinal clinical information about the patient's health status is typically needed to sufficiently demonstrate a normal inability to leave the home and that leaving home requires a considerable and taxing effort. Such clinical information about the patient's overall health status may include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.

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; or
- 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, attendance at a family reunion, funeral, graduation, or other infrequent or unique event 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.

Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists are listed below.

- A patient paralyzed from a stroke who is confined to a wheelchair or requires the aid of crutches in order to walk.

- A patient who is blind or senile and requires the assistance of another person in leaving their place of residence.

- A patient who has lost the use of their upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and requires the assistance of another individual to leave their place of residence.

- A patient in the late stages of ALS or neurodegenerative disabilities. In determining whether the patient has the general inability to leave the home and leaves the home only infrequently or for periods of short duration, it is necessary (as is the case in determining whether skilled nursing services are intermittent) to look at the patient's condition over a period of time rather than for short periods within the home health stay. For example, a patient may leave the home (meeting both criteria listed above) more frequently during a short period when the patient has multiple appointments with health care professionals and medical tests in 1 week. So long as the patient's overall condition and experience is such that he or she meets these qualifications, he or she should be considered confined to the home.

- A patient who has just returned from a hospital stay involving surgery, who may be suffering from resultant weakness and pain because of the surgery and; therefore, their actions may be restricted by their physician *or allowed practitioner* 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.).

- A patient with arteriosclerotic heart disease of such severity that they must avoid all stress and physical activity.

- A patient with a psychiatric illness that is manifested in part by a refusal to leave home or is of such a nature that it would not be considered safe for the patient to leave home unattended, even if they have no physical limitations.

The aged person who does not often travel from home because of frailty and insecurity brought on by advanced age would not be considered confined to the home for purposes of receiving home health services unless they meet one of the above conditions.

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 an individual involve the use of such equipment, the HHA may make arrangements with a hospital, SNF, or a rehabilitation center to provide these services on an outpatient basis. (See §50.6.) However, even in these situations, for the services to be covered as home health services the patient must be considered confined to home and meet both criteria listed above.

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

30.2 - Services Are Provided Under a Plan of Care Established and Approved by a Physician *or Allowed Practitioner*

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

30.2.1 – Definition of an Allowed Practitioner

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Allowed practitioners in addition to physicians, can certify and recertify beneficiaries for eligibility, order home health services, and establish and review the care plan. Allowed practitioners are defined at § 484.2 as a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part. NPs, CNSs, and PAs are required to practice in accordance with state law in the state in which the individual performs

such services. Individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required.

30.2.*2* - Content of the Plan of Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The HHA must be acting upon a physician *or allowed practitioner* plan of care that meets the requirements of this section for HHA services to be covered. For HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment. In addition, the plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in 42 CFR 484.60(a) that establish the need for such services. All care provided must be in accordance with the plan of care.

If the plan of care includes a course of treatment for therapy services:

- The course of therapy treatment must be established by the physician *or allowed practitioner* after any needed consultation with the qualified therapist;
- The plan must include measurable therapy treatment goals which pertain directly to the patient's illness or injury, and the patient's resultant impairments;
- The plan must include the expected duration of therapy services; and
- The plan must describe a course of treatment which is consistent with the qualified therapist's assessment of the patient's function.

30.2.*3* - Specificity of Orders

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01-11-21)

The orders on the plan of care must indicate 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 1:

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; 3 times per week for 4 weeks; and 2 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 services is provided to home health patients under a home health plan of care. When a range of visits is ordered, the upper limit of the range is considered the specific frequency.

EXAMPLE 2:

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 *or allowed practitioner* order would have to be obtained.

30.2.*4* - Who Signs the Plan of Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The physician *or allowed practitioner* who signs the plan of care must be qualified to sign the certification as described in 42 CFR 424.22.

30.2.*5* - Timeliness of Signature

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

A. Initial Percentage Payment

If a physician *or allowed practitioner* signed plan of care is not available at the beginning of the 30-day period, the HHA may submit a RAP for the initial percentage payment based on physician *or allowed practitioner* verbal orders OR a referral prescribing detailed orders for the services to be rendered that is signed and dated by the physician *or allowed practitioner*. If the RAP submission is based on 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 *or allowed practitioner's* orders and the date received per 42 CFR 409.43), and the plan of care is copied and immediately submitted to the physician *or allowed practitioner*. A billable visit must be rendered prior to the submission of a RAP.

B. Final Percentage Payment

The plan of care must be signed and dated by a physician *or allowed practitioner* as described who meets the certification and recertification requirements of 42 CFR 424.22 and before the claim for each 30-day period for services is submitted for the final percentage payment. Any changes in the plan of care must be signed and dated by a physician *or allowed practitioner*.

30.2.*6* - Use of Oral (Verbal) Orders

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

When services are furnished based on a physician *or allowed practitioner'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 *or allowed practitioner* before the HHA bills for the care in the same way as the plan of care.

Services which are provided from the beginning of the 60-day certification period based on a request for anticipated payment and before the physician *or allowed practitioner* signs the plan of care are considered to be provided under a plan of care established and approved by the physician *or allowed practitioner* 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.

Services that are provided in the subsequent 60-day certification period are considered 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 the plan of care, but before the acquisition of an oral order or a signed plan of care are not considered provided under a plan of care.

EXAMPLE 1:

The HHA acquires an oral order for I.V. medication administration for a patient to be performed on August 1. The HHA provides the I.V. medication administration August 1 and evaluates the patient's need for continued care. The physician *or allowed practitioner* signs the plan of care for the I.V. medication administration on August 15. The visit is covered since it is considered provided under a plan of care established and approved by the physician *or allowed practitioner*, and the HHA had acquired an oral order prior to the delivery of services.

EXAMPLE 2:

The patient is under a plan of care in which the physician *or allowed practitioner* orders I.V. medication administration every 2 weeks. The last day covered by the initial plan of care is July 31. The patient's next I.V. medication administration is scheduled for August 5 and the physician *or allowed practitioner* signs the plan of care for the new period on August 1. The I.V. medication administration on August 5 was provided under a plan of care established and approved by the physician *or allowed practitioner*.

EXAMPLE 3:

The patient is under a plan of care in which the physician *or allowed practitioner* orders I.V. medication administration every 2 weeks. The last day covered by the plan of care is July 31. The patient's next I.V. medication administration is scheduled for August 5 and the physician *or allowed practitioner* does not sign the plan of care until August 6. The HHA acquires an oral order for the I.V. medication administration before the August 5 visit, and therefore the visit is considered to be provided under a plan of care established and approved by the physician *or allowed practitioner*.

Any increase in the frequency of services or addition of new services during a 60-day certification must be authorized by a physician *or allowed practitioner* by way of a written or oral order prior to the provision of the increased or additional services

30.2.*7* - Frequency of Review of the Plan of Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The plan of care must be reviewed and signed by the physician *or allowed practitioner* 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 *or allowed practitioner* and the date of review.

30.2.*8* - Facsimile Signatures

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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.

30.2.*9* - Alternative Signatures

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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.

30.2.*10* - Termination of the Plan of Care - Qualifying Services

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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 certification period since these are qualifying services for the home health benefit. An exception is if the physician *or allowed practitioner* documents that the interval without such care is appropriate to the treatment of the patient's illness or injury.

30.2.*11* - Sequence of Qualifying Services and Other Medicare Covered Home Health Services

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Once patient eligibility has been confirmed and the plan of care contains physician *or allowed practitioner* 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 certification period 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).

NOTE: Dependent services provided after the final qualifying skilled service are not covered under the home health benefit, except when the dependent service was not followed by a qualifying skilled service due to unexpected inpatient admission, death of the patient, or some other unanticipated event.

30.3 - Under the Care of a Physician *or Allowed Practitioner*

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The patient must be under the care of a physician *or allowed practitioner* who is qualified to sign the certification and plan of care in accordance with 42 CFR 424.22.

A patient is expected to be under the care of the physician *or allowed practitioner* who signs the plan of care. It is expected that in most instances, the physician *or allowed practitioner* who certifies the patient's eligibility for Medicare home health services, in accordance with §30.5 below, will be the same physician *or allowed practitioner* who establishes and signs the plan of care.

30.4 - Needs 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 Has Continued Need for Occupational Therapy

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The patient must need one of the following types of services:

1. Skilled nursing care that is

    - Reasonable and necessary as defined in §40.1;
    - Needed on an "intermittent" basis as defined in §40.1.3; and
    - Not solely needed for venipuncture for the purposes of obtaining blood sample as defined in §40.1.2.13;or

2. Physical therapy as defined in §40.2.2; or

3. Speech-language pathology services as defined in §40.2.3; or

4. Have a continuing need for occupational therapy as defined in §§40.2.4.

The patient has a continued need for occupational therapy when:

1. The services which the patient requires meet the definition of "occupational therapy" services of §40.2.4, and

2. 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 cerebrovascular accident (CVA) has an initial plan of care that called for physical therapy, speech-language pathology services, occupational therapy, and home health aide services. In the next certification period, the physician *or allowed practitioner* 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 for home health services, including home health aide services (presuming that all other qualifying criteria are met), because in the prior certification period the beneficiary's eligibility for home health services was established by virtue of prior needs for physical therapy and speech-language pathology, and occupational therapy was initiated while the patient still required physical therapy and/or speech language-pathology.

30.5 - Physician *or Allowed Practitioner* Certification and Recertification of Patient Eligibility for Medicare Home Health Services

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The HHA must be acting upon a plan of care as described in §30.2, and a physician *or allowed practitioner* certification or recertification that meets the requirements of the following sections in order for HHA services to be covered.

30.5.1 - Physician *or Allowed Practitioner* Certification

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

A certification (versus recertification) is considered to be anytime that a Start of Care OASIS is completed to initiate care. In such instances, a physician *or allowed practitioner* must certify (attest) that:

1. The home health services are or were needed because the patient is or was confined to the home as defined in §30.1.1;

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), or physical therapy, or speech-language pathology services. Where a patient's sole skilled service need is for skilled oversight of unskilled services (management and evaluation of the care plan as defined in §40.1.2.2), the physician *or allowed practitioner* must include a brief narrative describing the clinical justification of this need as part of the certification, or as a signed addendum to the certification;

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

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

5. For episodes/periods with starts of care beginning January 1, 2011 and later, in accordance with §30.5.1.1 below, a face-to-face encounter occurred no more than 90 days prior to or within 30 days after the start of the home health care, was related to the primary reason the patient requires home health services, and was performed by a *physician or non-physician practitioner*. The certifying physician *or allowed practitioner* must also document the date of the encounter.

Example Certification Statement:

I certify that this patient is confined to his/her home and needs intermittent skilled nursing care, physical therapy and/or speech therapy or continues to need occupational therapy. The patient is under my care, and I have authorized services on this plan of care and will periodically review the plan. The patient had a face-to-face encounter with a *physician or an* allowed *non-physician practitioner* on *11/01/2020* and the encounter was related to the primary reason for home health care.

Physician *or allowed practitioner's* Signature and Date Signed: **John Doe, MD 11/05/*2020***

Physician *or Allowed Practitioner's* Name and Address

John Doe, MD
2121 Washington Pkwy
Suite 220
Washington, DC 20000

NOTE: This represents one example of a valid certification statement. Certification statements can be included in varying forms or formats as long as the content requirements (#1-5 above) for the certification are met.

If the patient is starting home health directly after discharge from an acute/post-acute care setting where the physician *or allowed practitioner*, with privileges, that cared for the patient in that setting is certifying the patient's eligibility for the home health benefit, but will not be following the patient after discharge, then the certifying physician *or allowed practitioner* must identify the community physician *or allowed practitioner* who will be following the patient after discharge. One of the criteria that must be met for a patient to be considered eligible for the home health benefit is that the patient must be under the care of a physician *or allowed practitioner* (number 4 listed above). Otherwise, the certification is not valid.

The certification must be complete prior to when an HHA bills Medicare for reimbursement; however, physicians *and allowed practitioners* should complete the certification when the plan of care is established, or as soon as possible thereafter. This is longstanding CMS policy as referenced in Pub 100-01, Medicare General Information, Eligibility, and Entitlement Manual, chapter 4, section 30.1. It is not acceptable for HHAs to wait until the end of a 60-day certification period to obtain a completed certification/recertification.

30.5.1.1 – Face-to-Face Encounter

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

1. Allowed Provider Types

As part of the certification of patient eligibility for the Medicare home health benefit, a face-to-face encounter with the patient must be performed by the certifying physician *or allowed practitioner* himself or herself, a physician *or allowed practitioner* that cared for the patient in the acute or post-acute care facility (with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health) or an allowed non-physician practitioner (NPP).

NPPs who are allowed to perform the encounter are:

- A nurse practitioner or a clinical nurse specialist working in accordance with State law and in collaboration with the certifying physician or in collaboration with an acute or post-acute care physician, with privileges, who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health;

- A certified nurse midwife, as authorized by State law, under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health;

- A physician assistant under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

NPPs performing the encounter are subject to the same financial restrictions with the HHA as the certifying physician, as described in 42 CFR 424.22(d).

2. Timeframe Requirements

- The encounter must occur no more than 90 days prior to the home health start of care date or within 30 days after the start of care.

- In situations when a physician *or allowed practitioner* orders home health care for the patient based on a new condition that was not evident during a visit within the 90 days prior to start of care, the physician or an allowed NPP must see the patient again within 30 days after admission. Specifically, if a patient saw the physician or NPP within the 90 days prior to start of care, another encounter would be needed if the patient's condition had changed to the extent that standards of practice would indicate that the physician or a non-physician practitioner should examine the patient in order to establish an effective treatment plan.

3. Exceptional Circumstances

When a home health patient dies shortly after admission, before the face-to-face encounter occurs, if the contractor determines a good faith effort existed on the part of the HHA to facilitate/coordinate the encounter and if all other certification requirements are met, the certification is deemed to be complete.

4. Telehealth

The face-to-face encounter can be performed via a telehealth service, in an approved originating site. An originating site is considered to be the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in a rural health professional shortage area or in a county outside of a Metropolitan Statistical Area.

Entities that participate in a Federal telemedicine demonstration project approved by (or receiving funding from) the Secretary of the Department of Health and Human Services as of December 31, 2000, qualify as originating sites regardless of geographic location.

The originating sites authorized by law are:

- The office of a physician or practitioner;
- Hospitals;
- Critical Access Hospitals (CAH);
- Rural Health Clinics (RHC);
- Federally Qualified Health Centers (FQHC);

- Hospital-based or CAH-based Renal Dialysis Centers (including satellites);
- Skilled Nursing Facilities (SNF); and
- Community Mental Health Centers (CMHC).

30.5.1.2 – Supporting Documentation Requirements

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

As of January 1, 2015, documentation in the certifying physician *or allowed practitioner's* medical records and/or the acute /post-acute care facility's medical records (if the patient was directly admitted to home health) will be used as the basis upon which patient eligibility for the Medicare home health benefit will be determined. Documentation from the certifying physician *or allowed practitioner's* medical records and/or the acute /post-acute care facility's medical records (if the patient was directly admitted to home health) used to support the certification of home health eligibility must be provided, upon request, to the home health agency, review entities, and/or the Centers for Medicare and Medicaid Services (CMS). In turn, an HHA must be able to provide, upon request, the supporting documentation that substantiates the eligibility for the Medicare home health benefit to review entities and/or CMS. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

The certifying physician *or allowed practitioner* and/or the acute/post-acute care facility medical record (if the patient was directly admitted to home health) for the patient must contain information that justifies the referral for Medicare home health services. This includes documentation that substantiates the patient's:

- Need for the skilled services; and
- Homebound status;

The certifying physician *or allowed practitioner* and/or the acute/post-acute care facility medical record (if the patient was directly admitted to home health) for the patient must contain the actual clinical note for the face-to-face encounter visit that demonstrates that the encounter:

- Occurred within the required timeframe,
- Was related to the primary reason the patient requires home health services; and
- Was performed by an allowed provider type.

This information can be found most often in clinical and progress notes and discharge summaries. While the face-to-face encounter must be related to the primary reason for home health services, the patient's skilled need and homebound status can be substantiated through an examination of all submitted medical record documentation from the certifying physician *or allowed practitioner*, acute/post-acute care facility, and/or HHA (see below). The synthesis of progress notes, diagnostic findings, medications, nursing notes, etc., help to create a longitudinal clinical picture of the patient's health status.

- Information from the HHA, such as the plan of care required per 42 CFR §409.43 and the initial and/or comprehensive assessment of the patient required per 42 CFR §484.55, can be incorporated into the certifying physician *or allowed practitioner's* medical record for the patient and used to support the patient's homebound status and need for skilled care. However, this information must be corroborated by other medical record entries in the certifying physician *or allowed practitioner's* and/or the acute/post-acute care facility's medical record for the patient. This means that the appropriately incorporated HHA information, along with the certifying physician *or allowed practitioner's* and/or the acute/post-acute care facility's medical record, creates a clinically consistent picture that the patient is eligible for Medicare home health services.

- The certifying physician *or allowed practitioner* demonstrates the incorporation of the HHA information into his/her medical record for the patient by signing and dating the material. Once incorporated, the documentation from the HHA, in conjunction with the certifying physician or

allowed practitioner and/or acute/post-acute care facility documentation, must substantiate the patient's eligibility for home health services.

30.5.2 - Physician *or Allowed Practitioner* Recertification

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

At the end of the 60-day certification, a decision must be made whether or not to recertify the patient for a subsequent 60-days. An eligible beneficiary who qualifies for a subsequent 60-day certification would start the subsequent 60-day certification on day 61. Under HH PPS, the plan of care must be reviewed and signed by the physician *or allowed practitioner* every 60 days unless one of the following occurs:

- A beneficiary transfers to another HHA; or
- A discharge and return to home health during the 60-day certification.

For recertification of home health services, the physician *or allowed practitioner* must certify (attest) that:

1. The home health services are or were needed because the patient is or was confined to the home as defined in §30.1;

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), or physical therapy, or speech-language pathology services; or continues to need occupational therapy after the need for skilled nursing care, physical therapy, or speech-language pathology services ceased. Where a patient's sole skilled service need is for skilled oversight of unskilled services (management and evaluation of the care plan as defined in §40.1.2.2), the physician *or allowed practitioner* must include a brief narrative describing the clinical justification of this need as part of the recertification, or as a signed addendum to the recertification;

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

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

Medicare does not limit the number of continuous 60-day recertifications for beneficiaries who continue to be eligible for the home health benefit. The certification may cover a period less than but not greater than 60 days. Because the updated home health plan of care must include the frequency and duration of visits to be made, the physician *or allowed practitioner* does not have to estimate how much longer skilled services will be needed for the recertification.

30.5.3 - Who May Sign the Certification or Recertification

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The physician *or allowed practitioner* who signs the certification or recertification must be permitted to do so by 42 CFR 424.22. *A physician or allowed practitioner in the same group practice as the certifying physician or allowed practitioner who established the home health plan of care and the certification/recertification statement, may sign in place of the physician or allowed practitioner when he/she is unavailable. The HHA is responsible for ensuring that the physician or allowed practitioner who signs the plan of care and certification/recertification statement practices in the same group practice as the physician or allowed practitioner who established the plan of care and completed the certification. The physician or allowed practitioner that performed the required face-to-face encounter must sign the certification of eligibility, unless the patient is directly admitted to home health care from an acute or post-acute care facility and the encounter was performed by a physician or allowed practitioner in such setting.*

30.5.4 – Physician *or Allowed Practitioner* Billing for Certification and Recertification

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Certification and recertification claims are Part B claims paid for under the Physician Fee Schedule. These claims are billed using HCPCS codes G0180 (certification) or G0179 (re-certification). The descriptions of these two codes indicate that they are used to bill for certification or recertification of patient eligibility "for Medicare-covered home health services under a home health plan of care (patient not present), including contacts with the HHA and review of reports of patient status required by physicians *or allowed practitioners* to affirm the initial implementation of the plan of care that meets patient's needs, per certification period". As noted above, these codes are for certification or recertification for Medicare-covered home health services. If there are no Medicare-covered home health services, these codes should not be billed or paid. As such, claims for certification/recertification of eligibility for home health services (G0180 and G0179, respectively) will not be covered if the HHA claim itself was non-covered because the certification/recertification of eligibility was not complete or because there was insufficient documentation to support that the patient was eligible for the Medicare home health benefit.

40 - Covered Services Under a Qualifying Home Health Plan of Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Section 1861(m)of the Act governs the Medicare home health services that may be provided to eligible beneficiaries by or under arrangements made by a participating home health agency (HHA). Section 1861(m) describes home health services as

- Part-time or intermittent skilled nursing care (other than solely venipuncture for the purposes of obtaining a blood sample);
- Part-time or intermittent home health aide services;
- Physical therapy;
- Speech-language pathology;
- Occupational therapy;
- Medical social services;
- Medical supplies (including catheters, catheter supplies, ostomy bags, supplies related to ostomy care, and a covered osteoporosis drug (as defined in §1861(kk of the Act), but excluding other drugs and biologicals);
- Durable medical equipment while under the plan of care established by physician *or allowed practitioner*;
- Medical services provided by an intern or resident-in-training under an approved teaching program of the hospital in the case of an HHA which is affiliated or under common control with a hospital; and
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

The term "part-time or intermittent" for purposes of coverage under §1861(m) of the Act 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 per week). See §50.7.

For any home health services to be covered by Medicare, the patient must meet the qualifying criteria as specified in §30, including having a need for skilled nursing care on an intermittent basis, physical therapy, speech-language pathology services, or a continuing need for occupational therapy as defined in this section.

40.1.1 - General Principles Governing Reasonable and Necessary Skilled Nursing Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

If all other eligibility and coverage requirements under the home health benefit are met, skilled nursing services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a registered nurse or, when provided by regulation, a licensed practical (vocational) nurse ("skilled care") are necessary. Skilled nursing services are covered where such skilled nursing services are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided. When, however, the individualized assessment does not demonstrate such a necessity for skilled care, including when the services needed do not require skilled nursing care because they could safely and effectively be performed by the patient or unskilled caregivers, such services will not be covered under the home health benefit.

Skilled nursing care is necessary only when (a) the particular patient's special medical complications require the skills of a registered nurse or, when provided by regulation, a licensed practical nurse to perform a type of service that would otherwise be considered non-skilled; or (b) the needed services are of such complexity that the skills of a registered nurse or, when provided by regulation, a licensed practical nurse are required to furnish the services. To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel as provided by regulation, including 42 C.F.R. 409.32.

Some services may be classified as a skilled nursing service on the basis of complexity alone (e.g., intravenous and intramuscular injections or insertion of catheters) and, if reasonable and necessary to the treatment of the patient's illness or injury, would be covered on that basis. If a service can be safely and effectively performed (or self-administered) by an unskilled person, without the direct supervision of a nurse, the service cannot be regarded as a skilled nursing service although a nurse actually provides the service. However, in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered a skilled nursing service. This would occur when the patient's condition is such that the service can be safely and effectively provided only by a nurse. A service is not considered a skilled nursing service merely because it is performed by or under the supervision of a nurse. The unavailability of a competent person to provide a non-skilled service, regardless of the importance of the service to the patient, does not make it a skilled service when a nurse provides the service.

A service that, by its nature, requires the skills of a nurse to be provided safely and effectively continues to be a skilled service even if it is taught to the patient, the patient's family, or other caregivers.

The skilled nursing service must be reasonable and necessary to the diagnosis and treatment of the patient's illness or injury within the context of the patient's unique medical condition. To be considered reasonable and necessary for the diagnosis or treatment of the patient's illness or injury, the services must be consistent with the nature and severity of the illness or injury, the patient's particular medical needs, and accepted standards of medical and nursing practice. The determination of whether the services are reasonable and necessary should be made in consideration that a physician *or allowed practitioner* has determined that the services ordered are reasonable and necessary. The services must, therefore, be viewed from the perspective of the condition of the patient when the services were ordered and what was, at that time, reasonably expected to be appropriate treatment for the illness or injury throughout the certification period.

A patient's overall medical condition, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time, should be considered in deciding whether skilled services are needed. A patient's diagnosis should never be the sole factor in deciding that a service the

patient needs is either skilled or not skilled. Skilled care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable.
As is outlined in home health regulations, as part of the home health agency (HHA) Conditions of Participation (CoPs), the clinical record of the patient must contain progress and clinical notes. Additionally, in Pub. 100-04, Medicare Claims Processing Manual, Chapter 10; "Home Health Agency Billing", instructions specify that for each claim, HHAs are required to report all services provided to the beneficiary during each 30-day period, which includes reporting each visit in line-item detail. As such, it is expected that the home health records for every visit will reflect the need for the skilled medical care provided. These clinical notes are also expected to provide important communication among all members of the home care team regarding the development, course and outcomes of the skilled observations, assessments, treatment and training performed. Taken as a whole then, the clinical notes are expected to tell the story of the patient's achievement towards his/her goals as outlined in the Plan of Care. In this way, the notes will serve to demonstrate why a skilled service is needed.

Therefore the home health clinical notes must document as appropriate:

- the history and physical exam pertinent to the day's visit, (including the response or changes in behavior to previously administered skilled services) and the skilled services applied on the current visit, and
- the patient/caregiver's response to the skilled services provided, and
- the plan for the next visit based on the rationale of prior results,
- a detailed rationale that explains the need for the skilled service in light of the patient's overall medical condition and experiences,
- the complexity of the service to be performed, and
- any other pertinent characteristics of the beneficiary or home

Clinical notes should be written so that they adequately describe the reaction of a patient to his/her skilled care. Clinical notes should also provide a clear picture of the treatment, as well as "next steps" to be taken. Vague or subjective descriptions of the patient's care should not be used. For example, terminology such as the following would not adequately describe the need for skilled care:

- Patient tolerated treatment well
- Caregiver instructed in medication management
- Continue with POC

Objective measurements of physical outcomes of treatment should be provided and/or a clear description of the changed behaviors due to education programs should be recorded in order that all concerned can follow the results of the applied services.

EXAMPLE 1:

The presence of a plaster cast on an extremity generally does not indicate a need for skilled nursing care. However, the patient with a preexisting peripheral vascular or circulatory condition might need skilled nursing care to observe for complications, monitor medication administration for pain control, and teach proper skin care to preserve skin integrity and prevent breakdown. The documentation must support the severity of the circulatory condition that requires skilled care. The clinical notes for each home health visit should document the patient's skin and circulatory examination as well as the patient and/or caregiver application of the educational principles taught since the last visit. The plan for the next visit should describe the skilled services continuing to be required.

EXAMPLE 2:

The condition of a patient, who has irritable bowel syndrome or is recovering from rectal surgery, may be such that he or she can be given an enema safely and effectively only by a nurse. If the enema were necessary to treat the illness or injury, then the visit would be covered as a skilled nursing visit. The documentation must support the skilled need for the enema, and the plan for future visits based on this information.

EXAMPLE 3:

Giving a bath does not ordinarily require the skills of a nurse and, therefore, would not be covered as a skilled nursing service unless the patient's condition is such that the bath could be given safely and effectively only by a nurse (as discussed in §30.1 above).

EXAMPLE 4:

A patient with a well-established colostomy absent complications may require assistance changing the colostomy bag because they cannot do it themselves and there is no one else to change the bag. Notwithstanding the need for the routine colostomy care, changing the colostomy bag does not become a skilled nursing service when the nurse provides it.

EXAMPLE 5:

A patient was discharged from the hospital with an open draining wound that requires irrigation, packing, and dressing twice each day. The HHA has taught the family to perform the dressing changes. The HHA continues to see the patient for the wound care that is needed during the time that the family is not available and willing to provide the dressing changes. The wound care continues to be skilled nursing care, notwithstanding that the family provides it part of the time, and may be covered as long as the patient requires it.

EXAMPLE 6:

A physician has ordered skilled nursing visits for a patient with a hairline fracture of the hip. The home health record must document the reason skilled services are required and why the nursing visits are reasonable and necessary for treatment of the patient's hip injury.

EXAMPLE 7:

A physician has ordered skilled nursing visits for teaching of self-administration and self-management of the medication regimen for a patient, newly diagnosed, with diabetes mellitus in the home health plan of care. Each visit’s documentation must describe the patient’s progress in this activity.

EXAMPLE 8:

Following a cerebrovascular accident (CVA), a patient has an in-dwelling Foley catheter because of urinary incontinence, and is expected to require the catheter for a long and indefinite period. The medical condition of the patient must be described and documented to support the need for nursing skilled services in the home health plan of care. Periodic visits to change the catheter as needed, treat the symptoms of catheter malfunction, and teach proper catheter care would be covered as long as they are reasonable and necessary, although the patient is stable, even if there is an expectation that the care will be needed for a long and indefinite period. However, at every home health visit, the patient’s current medical condition must be described and there must be documentation to support the need for continued skilled nursing services.

EXAMPLE 9:

A patient with advanced multiple sclerosis undergoing an exacerbation of the illness needs skilled teaching of medications, measures to overcome urinary retention, and the establishment of a program designed to minimize the adverse impact of the exacerbation. The clinical notes for each home health visit must describe why skilled nursing services were required. The skilled nursing care received by the patient would be covered despite the chronic nature of the illness.

EXAMPLE 10:

A patient with malignant melanoma is terminally ill, and requires skilled observation, assessment, teaching, and treatment. The patient has not elected coverage under Medicare's hospice benefit. The documentation should describe the goal of the skilled nursing intervention, and at each visit the services provided should support that goal. The skilled nursing care that the patient requires would be covered, notwithstanding that the condition is terminal, because the documentation and description must support that the needed services required the skills of a nurse.

40.1.2.8 - Wound Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Care of wounds, (including, but not limited to, ulcers, burns, pressure sores, open surgical sites, fistulas, tube sites, and tumor erosion sites) when the skills of a licensed nurse are needed to provide safely and effectively the services necessary to treat the illness or injury, is considered to be a skilled nursing service. For skilled nursing care to be reasonable and necessary to treat a wound, the size, depth, nature of drainage (color, odor, consistency, and quantity), and condition and appearance of the skin surrounding the wound must be documented in the clinical findings so that an assessment of the need for skilled nursing care can be made. This includes whether wound care is performed via dressing changes, NPWT using conventional DME systems or NPWT using a disposable device. Coverage or denial of skilled nursing visits for wound care may not be based solely on the stage classification of the wound, but rather must be based on all of the documented clinical findings. Moreover, the plan of care must contain the specific instructions for the treatment of the wound. Where the physician *or allowed practitioner* has ordered appropriate active treatment (e.g., sterile or complex dressings, NPWT, administration of prescription medications, etc.) of wounds with the following characteristics, the skills of a licensed nurse are usually reasonable and necessary:

- Open wounds which are draining purulent or colored exudate or have a foul odor present or for which the patient is receiving antibiotic therapy;
- Wounds with a drain or T-tube that require shortening or movement of such drains;
- Wounds which require irrigation or instillation of a sterile cleansing or medicated solution into several layers of tissue and skin and/or packing with sterile gauze;
- Recently debrided ulcers;
- Pressure sores (decubitus ulcers) with the following characteristics:
    - There is partial tissue loss with signs of infection such as foul odor or purulent drainage; or
    - There is full thickness tissue loss that involves exposure of fat or invasion of other tissue such as muscle or bone.

      NOTE: Wounds or ulcers that show redness, edema, and induration, at times with epidermal blistering or desquamation do not ordinarily require skilled nursing care.
- Wounds with exposed internal vessels or a mass that may have a proclivity for hemorrhage when a dressing is changed (e.g., post radical neck surgery, cancer of the vulva);

- Open wounds or widespread skin complications following radiation therapy, or which result from immune deficiencies or vascular insufficiencies;

- Post-operative wounds where there are complications such as infection or allergic reaction or where there is an underlying disease that has a reasonable potential to adversely affect healing (e.g., diabetes);

- Third degree burns, and second degree burns where the size of the burn or presence of complications causes skilled nursing care to be needed;

- Skin conditions that require application of nitrogen mustard or other chemotherapeutic medication that present a significant risk to the patient;

- Other open or complex wounds that require treatment that can only be provided safely and effectively by a licensed nurse.

EXAMPLE 1:

A patient has a second-degree burn with full thickness skin damage on the back. The wound is cleansed, followed by an application of Sulfamylon. While the wound requires skilled monitoring for signs and symptoms of infection or complications, the dressing change requires skilled nursing services. The home health record at each visit must document the need for the skilled nursing services.

EXAMPLE 2:

A patient experiences a decubitus ulcer where the full thickness tissue loss extends through the dermis to involve subcutaneous tissue. The wound involves necrotic tissue with a physician's order to apply a covering of a debriding ointment following vigorous irrigation. The wound is then packed loosely with wet to dry dressings or continuous moist dressing and covered with dry sterile gauze. Skilled nursing care is necessary for proper treatment. The home health record at each visit must document the need for the skilled nursing services.

NOTE: This section relates to the direct, hands on skilled nursing care provided to patients with wounds, including any necessary dressing changes on those wounds. While a wound might not require this skilled nursing care, the wound may still require skilled monitoring for signs and symptoms of infection or complication (see §40.1.2.1) or for skilled teaching of wound care to the patient or the patient's family (see §40.1.2.3). For an example of when wound care is provided separately from the furnishing of NPWT using a disposable device, see §50.4.4.

40.1.2.10 - Heat Treatments

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Heat treatments that have been specifically ordered by a physician *or allowed practitioner* 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 a skilled nursing service.

40.1.2.13 - Venipuncture

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Effective February 5, 1998, 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 under a home health plan of care.

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act specifically exclude venipuncture, as a basis for qualifying for Medicare home health services if this is the sole skilled service the beneficiary requires. However, the Medicare home health benefit will continue to pay for a blood draw if the beneficiary has a need for another qualified skilled service and meets all home health eligibility criteria. This specific requirement applies to home health services furnished on or after February 5, 1998.

For venipuncture to be reasonable and necessary:

1. The physician *or allowed practitioner* 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 and monitoring the treatment must also be reasonable and necessary.

2. 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.

3. The home health record must document the rationale for the blood draw as well as the results.

   Examples of reasonable and necessary venipuncture for stabilized patients include, but are not limited to those described below.

   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 and it is therefore 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 noninsulin dependent diabetic would require FBS more frequently than once per month if ordered by the physician *or allowed practitioner*.

      - Where there is a new diagnosis or where 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 noninsulin 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 *or allowed practitioner*.

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

- Where the results remain within nontherapeutic ranges, there must be specific documentation of the factors that indicate why continued monitoring is reasonable and necessary.

EXAMPLE: A patient with coronary artery disease was hospitalized with atrial fibrillation and subsequently discharged to the HHA with orders for anticoagulation therapy as well as other skilled nursing care. If indicated, monthly venipuncture to report prothrombin (protime) levels to the physician *or allowed practitioner* would be reasonable and necessary even though the patient's prothrombin time tests indicate essential stability. The home health record must document the rationale for the blood draw as well as the results.

40.1.2.15 - Psychiatric Evaluation, Therapy, and Teaching

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The evaluation, psychotherapy, and teaching 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 *or allowed practitioner*.

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 Medicare contractor will verify whether the patients meet the eligibility requirements specified in §30 and whether the HHA is primarily engaged in care and treatment of mental disease.

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 non-psychiatric 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. The home health record at each visit should document the need for the psychiatric skilled nursing services and treatment. The home health record must also reflect the patient/caregiver response to any interventions provided.

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, and 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 skilled nursing services are 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. The home health record at each visit should document the need for the psychiatric skilled nursing services and treatment. The home health record must also reflect the patient/caregiver response to any interventions provided.

40.1.3 - Intermittent Skilled Nursing Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The law, at §1861(m) of the Act defines intermittent, for the purposes of §§1814(a)(2) and 1835(a)(2)(A), as 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. The exception to the intermittent requirement is daily skilled nursing services for diabetics unable to administer their insulin (when there is no able and willing caregiver).

Since the need for "intermittent" skilled nursing care makes the patient eligible for other covered home health services, the Medicare contractor 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. The following are examples of the need for infrequent, yet intermittent, skilled nursing services:

1. The patient with an indwelling **silicone** catheter who generally needs a catheter change only at 90-day intervals;

2. The patient who experiences a fecal impaction (i.e., loss of bowel tone, restrictive mobility, and a breakdown in good health habits) and must receive care to manually relieve the impaction. Although these impactions are likely to recur, it is not possible to pinpoint a specific timeframe; or

3. The blind diabetic who self-injects insulin may have a medically predictable recurring need for a skilled nursing visit at least every 90 days. These visits, for example, would be to observe and determine the need for changes in the level and type of care which have been prescribed thus supplementing the physician or *allowed practitioner's* contacts with the patient.

There is a possibility that a physician *or allowed practitioner* 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 or *allowed practitioner* 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 §50.7) medically reasonable and necessary skilled nursing care 7 days a week for a short period of time (2 to 3 weeks). There may also be a few cases involving unusual circumstances where the patient's prognosis indicates the medical need for daily skilled services will extend 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, would usually not qualify for home health benefits.

40.2.1 - General Principles Governing Reasonable and Necessary Physical Therapy, Speech-Language Pathology Services, and Occupational Therapy

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

The service of a physical therapist, speech-language pathologist, or occupational therapist is a skilled therapy service if the inherent complexity of the service is such that it can be performed safely and/or effectively only by or under the general supervision of a skilled therapist. To be covered, assuming all other eligibility and coverage criteria have been met, the skilled services must also be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury. It is necessary to determine whether individual therapy services are skilled and whether, in view of the patient's overall condition, skilled management of the services provided is needed.

The development, implementation, management, and evaluation of a patient care plan based on the physician *or allowed practitioner's* orders constitute skilled therapy services when, because of the patient's clinical condition, those activities require the specialized skills, knowledge, and judgment of a qualified therapist to ensure the effectiveness of the treatment goals and ensure medical safety. Where the specialized skills, knowledge, and judgment of a therapist are needed to manage and periodically reevaluate the appropriateness of a maintenance program, such services would be covered, even if the skills of a therapist were not needed to carry out the activities performed as part of the maintenance program.

While a patient's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a patient's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by unskilled personnel.

A service that is ordinarily considered unskilled could be considered a skilled therapy service in cases where there is clear documentation that, because of special medical complications, skilled rehabilitation personnel are required to perform the service. However, the importance of a particular service to a patient or the frequency with which it must be performed does not, by itself, make an unskilled service into a skilled service.

Assuming all other eligibility and coverage criteria have been met, the skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury within the context of the patient's unique medical condition. To be considered reasonable and necessary for the treatment of the illness or injury:

a. The services must be consistent with the nature and severity of the illness or injury, the patient's particular medical needs, including the requirement that the amount, frequency, and duration of the services must be reasonable; and

b. The services must be considered, under accepted standards of medical practice, to be specific, safe, and effective treatment for the patient's condition, meeting the standards noted below. The home health record must specify the purpose of the skilled service provided.

To ensure therapy services are effective, at defined points during a course of treatment, for each therapy discipline for which services are provided, a qualified therapist (instead of an assistant) must perform the ordered therapy service. During this visit, the therapist must assess the patient using a method which allows for objective measurement of function and successive comparison of measurements. The therapist must document the measurement results in the clinical record. Specifically:

i. <u>Initial Therapy Assessment</u>

- For each therapy discipline for which services are provided, a qualified therapist (instead of an assistant) must assess the patient's function using a method which objectively measures activities of daily living such as, but not limited to, eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, using assistive devices, and mental and cognitive factors. The measurement results must be documented in the clinical record.

- Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must functionally assess the patient. The therapist must document the measurement results which correspond to the therapist's discipline and care plan goals in the clinical record.

ii. <u>Reassessment at least every 30 days (performed in conjunction with an ordered therapy service)</u>

- At least once every 30 days, for each therapy discipline for which services are provided, a qualified therapist (instead of an assistant) must provide the ordered therapy service, functionally reassess the patient, and compare the resultant measurement to prior assessment measurements. The therapist must document in the clinical record the measurement results along with the therapist's determination of the effectiveness of therapy, or lack thereof.

- For multi-discipline therapy cases, a qualified therapist from each of the disciplines must functionally reassess the patient. The therapist must document the measurement results which correspond to the therapist's discipline and care plan goals in the clinical record.

- The 30-day clock begins with the first therapy service (of that discipline) and the clock resets with each therapist's visit/assessment/measurement/documentation (of that discipline).

c. Services involving activities for the general welfare of any patient, e.g., general exercises to promote overall fitness or flexibility and activities to provide diversion or general motivation do not constitute skilled therapy. Unskilled individuals without the supervision of a therapist can perform those services.

d. Assuming all other eligibility and coverage requirements have been met, in order for therapy services to be covered, one of the following three conditions must be met:

1. The skills of a qualified therapist, or by a qualified therapist assistant under the supervision of a qualified therapist, are needed to restore patient function:

- To meet this coverage condition, therapy services must be provided with the expectation, based on the assessment made by the physician *or allowed practitioner* of the patient's

restorative potential that the condition of the patient will improve materially in a reasonable and generally predictable period of time. Improvement is evidenced by objective successive measurements.

- Therapy is not considered reasonable and necessary under this condition if the patient's expected restorative potential would be insignificant in relation to the extent and duration of therapy services required to reach such potential.

- Therapy is not required to effect improvement or restoration of function where a patient suffers a transient or easily reversible loss of function (such as temporary weakness following surgery) which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Therapy in such cases is not considered reasonable and necessary to treat the patient's illness or injury, under this condition. However, if the criteria for maintenance therapy described in (3) below is met, therapy could be covered under that condition.

2. The patient's clinical condition requires the specialized skills, knowledge, and judgment of a qualified therapist to establish or design a maintenance program, related to the patient's illness or injury, in order to ensure the safety of the patient and the effectiveness of the program, to the extent provided by regulation,

   - For patients receiving rehabilitative/restorative therapy services, if the specialized skills, knowledge, and judgment of a qualified therapist are required to develop a maintenance program, the expectation is that the development of that maintenance program would occur during the last visit(s) for rehabilitative/restorative treatment. The goals of a maintenance program would be to maintain the patient's current functional status or to prevent or slow further deterioration.

   - Necessary periodic reevaluations by a qualified therapist of the beneficiary and maintenance program are covered if the specialized skills, knowledge, and judgment of a qualified therapist are required.

   - Where a maintenance program is not established until after the rehabilitative/restorative therapy program has been completed, or where there was no rehabilitative/restorative therapy program, and the specialized skills, knowledge, and judgment of a qualified therapist are required to develop a maintenance program, such services would be considered reasonable and necessary for the treatment of the patient's condition in order to ensure the effectiveness of the treatment goals and ensure medical safety. When the development of a maintenance program could not be accomplished during the last visits(s) of rehabilitative/restorative treatment, the therapist must document why the maintenance program could not be developed during those last rehabilitative/restorative treatment visit(s).

   - When designing or establishing a maintenance program, the qualified therapist must teach the patient or the patient's family or caregiver's necessary techniques, exercises or precautions as necessary to treat the illness or injury. The instruction of the beneficiary or appropriate caregiver by a qualified therapist regarding a maintenance program is covered if the specialized skills, knowledge, and judgment of a qualified therapist are required. However, visits made by skilled therapists to a patient's home solely to train other HHA staff (e.g., home health aides) are not billable as visits since the HHA is responsible for ensuring that its staff is properly trained to perform any service it furnishes. The cost of a skilled therapist's visit for the purpose of training HHA staff is an administrative cost to the agency.

3. The skills of a qualified therapist or by a qualified therapist assistant under the supervision of a qualified therapist are needed to perform maintenance therapy:

- Coverage of therapy services to perform a maintenance program is not determined solely on the presence or absence of a beneficiary's potential for improvement from the therapy, but rather on the beneficiary's need for skilled care. Assuming all other eligibility and coverage requirements are met, skilled therapy services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist or by a qualified therapist assistant under the supervision of a qualified therapist ("skilled care") are necessary for the performance of a safe and effective maintenance program. Such a maintenance program to maintain the patient's current condition or to prevent or slow further deterioration is covered so long as the beneficiary requires skilled care for the safe and effective performance of the program. When, however, the individualized assessment does not demonstrate such a necessity for skilled care, including when the performance of a maintenance program does not require the skills of a therapist or by a qualified therapist assistant under the supervision of a qualified therapist because it could safely and effectively be accomplished by the patient or with the assistance of non-therapists, including unskilled caregivers, such maintenance services will not be covered.
- Further, under the standard set forth in the previous paragraph, skilled care is necessary for the performance of a safe and effective maintenance program only when (a) the particular patient's special medical complications require the skills of a qualified therapist or by a qualified therapist assistant under the supervision of a qualified therapist to perform a therapy service that would otherwise be considered non-skilled; or (b) the needed therapy procedures are of such complexity that the skills of a qualified therapist are required to perform the procedure.

e. The amount, frequency, and duration of the services must be reasonable.

As is outlined in home health regulations, as part of the home health agency (HHA) Conditions of Participation (CoPs), the clinical record of the patient must contain progress and clinical notes. Additionally, in Pub. 100-04, Medicare Claims Processing Manual, Chapter 10; "Home Health Agency Billing", instructions specify that for each claim, HHAs are required to report all services provided to the beneficiary during each 30-day period, this includes reporting each visit in line-item detail. As such, it is expected that the home health records for every visit will reflect the need for the skilled medical care provided. These clinical notes are also expected to provide important communication among all members of the home care team regarding the development, course and outcomes of the skilled observations, assessments, treatment and training performed. Taken as a whole then, the clinical notes are expected to tell the story of the patient's achievement towards his/her goals as outlined in the Plan of Care. In this way, the notes will serve to demonstrate why a skilled service is needed.

Therefore the home health clinical notes must document as appropriate:

- the history and physical exam pertinent to the day's visit , (including the response or changes in behavior to previously administered skilled services) and
- the skilled services applied on the current visit, and
- the patient/caregiver's immediate response to the skilled services provided, and
- the plan for the next visit based on the rationale of prior results.

Clinical notes should be written such that they adequately describe the reaction of a patient to his/her skilled care. Clinical notes should also provide a clear picture of the treatment, as well as "next steps" to be taken. Vague or subjective descriptions of the patient's care should not be used. For example terminology such as the following would not adequately describe the need for skilled care:

- Patient tolerated treatment well

- Caregiver instructed in medication management
- Continue with POC

Objective measurements of physical outcomes of treatment should be provided and/or a clear description of the changed behaviors due to education programs should be recorded in order that all concerned can follow the results of the applied services.

When the skilled service is being provided to either maintain the patient's condition or prevent or slow further deterioration, the clinical notes must also describe:

- A detailed rationale that explains the need for the skilled service in light of the patient's overall medical condition and experiences,
- the complexity of the service to be performed, and
- any other pertinent characteristics of the beneficiary or home.

50.2 - Home Health Aide Services

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

For home health aide services to be covered:

- The patient must meet the qualifying criteria as specified in §30;
- The services provided by the home health aide must be part-time or intermittent as discussed in §50.7;
- The services must meet the definition of home health aide services of this section; and
- The services must be reasonable and necessary to the treatment of the patient's illness or injury.

NOTE: A home health aide must be certified consistent the competency evaluation requirements.

The reason for the visits by the home health aide must be to provide hands-on personal care of the patient or services needed to maintain the patient's health or to facilitate treatment of the patient's illness or injury.

The physician *or allowed practitioner's* order should indicate the frequency of the home health aide services required by the patient. These services may include but are not limited to:

A. Personal Care

Personal care means:

1. Bathing, dressing, grooming, caring for hair, nail, and oral hygiene which are needed to facilitate treatment or to prevent deterioration of the patient's health, changing the bed linens of an incontinent patient, shaving, deodorant application, skin care with lotions and/or powder, foot care, and ear care; and

2. Feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the patient's condition, routine catheter care and routine colostomy care), assistance with ambulation, changing position in bed, assistance with transfers.

EXAMPLE 1:

A physician has ordered home health aide visits to assist the patient in personal care because the patient is recovering from a stroke and continues to have significant right side weakness that causes the patient to be unable to bathe, dress or perform hair and oral care. The plan of care established by the HHA nurse sets forth the specific tasks with which the patient needs assistance. Home health aide visits at an appropriate frequency would be reasonable and necessary to assist in these tasks.

EXAMPLE 2:

A physician ordered four home health aide visits per week for personal care for a multiple sclerosis patient who is unable to perform these functions because of increasing debilitation. The home health aide gave the patient a bath twice per week and washed hair on the other two visits each week. Only two visits are reasonable and necessary since the services could have been provided in the course of two visits.

EXAMPLE 3:

A physician ordered seven home health aide visits per week for personal care for a bed-bound, incontinent patient. All visits are reasonable and necessary because the patient has extensive personal care needs.

EXAMPLE 4:

A patient with a well-established colostomy forgets to change the bag regularly and has difficulty changing the bag. Home health aide services at an appropriate frequency to change the bag would be considered reasonable and necessary to the treatment of the illness or injury.

B. Simple Dressing Changes That Do Not Require the Skills of a Licensed Nurse
EXAMPLE 5:

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 Which 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 HHA staff performs the prefilling of insulin syringes, 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, 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 which 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. Provision of Services Incidental to Personal Care Services not 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 which do not meet the definition of a home health aide service (e.g., light cleaning, preparation of a meal, taking out the trash, shopping, etc.) 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 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 who 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."

50.4.1 - Medical Supplies

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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 30-day period payment rates. Supplies fit into two categories. They are classified as:

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

- **Nonroutine -** because they are needed to treat a patient's specific illness or injury in accordance with the physician *or allowed practitioner'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.

50.4.1.1 - The Law, Routine and Nonroutine Medical Supplies, and the Patient's Plan of Care

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

A. The Law

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 a 30-day period of care. The physician *or allowed practitioner's* orders in the plan of care must reflect all nonroutine medical supplies provided and used while the patient is under a home health plan of care. 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, there could be a circumstance where a physician *or allowed practitioner* could be uncomfortable with writing orders for a preexisting 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 *or allowed practitioner*.

Thus, all medical supplies are bundled while the patient is under a home health plan of care. 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. 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.

B. Relationship Between Patient Choice and Veterans Benefits

For veterans, both Medicare and Veteran's Administration (VA) benefits are primary. Therefore, the beneficiary who is a veteran has some choices in cases where the benefits overlap. The beneficiary, however, must select one or the other program as primary when obtaining active care. If the VA is selected as primary for home health care, then Medicare becomes a secondary payer. An HHA must provide the medical supplies a Medicare beneficiary needs no matter the payer; it is not obligated to provide medical supplies that are not needed. If a patient has medical supplies provided by the VA because of the patient's preference, then the HHA must not duplicate the supplies under Medicare. The beneficiary's choice is controlling. The HHA may not require the beneficiary to obtain or use medical supplies covered by the primary payer from any other source, including the VA.

C. 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, 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.

50.4.1.2 - Routine Supplies (Nonreportable)

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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 allowed practitioner* 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:

A. Dressings and Skin Care

- Swabs, alcohol preps, and skin prep pads;
- Tape removal pads;
- Cotton balls;
- Adhesive and paper tape;
- Nonsterile applicators; and
- 4 x 4's.

B. Infection Control Protection

- Nonsterile gloves;
- Aprons;
- Masks; and
- Gowns.

C. Blood Drawing Supplies

- Specimen containers.

D. Incontinence Supplies

- Incontinence briefs and Chux Covered in the normal course of a visit. For example, if a home health aide in the course of a bathing visit to a patient determines the patient requires an incontinence brief change, the incontinence brief in this example would be covered as a routine medical supply.

E. Other

- Thermometers; and
- 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 4x4s for major dressings.

50.4.1.3 - Nonroutine Supplies (Reportable)

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Nonroutine supplies are identified by the following conditions:

1. The HHA follows a consistent charging practice for Medicare and other patients receiving the item;

2. The item is directly identifiable to an individual patient;

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

4. The item is furnished at the direction of the patient's physician *or allowed practitioner* and is specifically identified in the plan of care.

All nonroutine supplies must be specifically ordered by the physician *or allowed practitioner* or the physician *or allowed practitioner's* order for services must require the use of the specific supplies to be effectively furnished.

The charge for nonroutine supplies is excluded from the per visit costs.

Examples of supplies that can be considered nonroutine include, but are not limited to:

1. Dressings/Wound Care

- Sterile dressings;
- Sterile gauze and toppers;
- Kling and Kerlix rolls;
- Telfa pads;
- Eye pads;
- Sterile solutions, ointments;
- Sterile applicators; and
- Sterile gloves.

2. I.V. Supplies

3. Ostomy Supplies

4. Catheters and Catheter Supplies

- Foley catheters; and
- Drainage bags, irrigation trays.

5. Enemas and Douches

6. Syringes and Needles

7. Home Testing

- Blood glucose monitoring strips; and
- Urine monitoring strips.

Consider other items that are often used by persons who are not ill or injured to be medical supplies only where:

- The item is recognized as having the capacity to serve a therapeutic or diagnostic purpose in a specific situation; and

- The item is required as a part of the actual physician *or allowed practitioner* 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 *or allowed practitioner'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 is 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. Supplies such as needles, syringes, and catheters that require administration by a nurse should not be left in the home between visits.

50.4.3 – Covered Osteoporosis Drugs

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Sections 1861(m) and 1861(kk) of the Act provide for coverage of FDA approved injectable drugs for the treatment of osteoporosis. These drugs are expected to be provided by an HHA to female beneficiaries who are currently receiving services under an open home health plan of care, who meet existing coverage criteria for the home health benefit and who meet the criteria listed below. These drugs are covered on a cost basis when provided by an HHA under the circumstances listed below.

The home health visit (i.e., the skilled nurse's visit) to administer the drug is covered under all fee-for-service Medicare (Part A or Part B) home health coverage rules (see section 30 above). Coverage of the drug is limited to female beneficiaries who meet each of the following criteria:

- The individual is eligible for Medicare Part B coverage of home health services (the nursing visit to perform the injection may be the individual's qualifying service);

- The individual sustained a bone fracture that a physician*, or allowed practitioner, or certified nurse midwife* certifies was related to post-menopausal osteoporosis; and

- The individual's physician*, or allowed practitioner, or certified nurse midwife* certifies that she is unable to learn the skills needed to self-administer the drug or is otherwise physically or mentally incapable of administering the drug, and that her family or caregivers are unable or unwilling to administer the drug.

This drug is considered part of the home health benefit under Part B. Therefore, Part B deductible and coinsurance apply regardless of whether home health visits for the administration of the drug are covered under Part A or Part B.

For instructions on billing for covered osteoporosis drugs, see Pub. 100-04, Medicare Claims Processing Manual, chapter 10, section 90.1.

50.5 - Services of Interns and Residents

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

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 *or allowed practitioner* 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:

- Approved by the Accreditation Council for Graduate Medical Education;
- In the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;
- 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
- 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.

70.2 - Counting Visits Under the Hospital and Medical Plans

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

A. 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. Though visits are provided under the HH benefit as part of 30-day periods, and periods are unlimited, each visit must be uniquely billed as a separate line item on a Medicare HH claim, and data on visit charges is still used in formulating payment rates.

B. 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 §30.

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 noncovered services). However, if all covered services could be provided in the course of one visit, only one visit may be covered.

EXAMPLES:

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 counted.

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 counted.

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 counted.

4. If an individual is taken to a hospital to receive outpatient therapy that could not be furnished in their own home (e.g., hydrotherapy) and, while at the hospital receives speech-language pathology services and other services, **two or more** visits would be charged.

5. Many home health agencies provide home health aide services on an hourly basis (ranging from 1 to 8 hours a day). However, in order to allocate visits properly against a patient's maximum allowable visits, home health aide services are to be counted in terms of visits. Thus, regardless of the number of continuous hours a home health aide spends in a patient's home on any given day, one "visit" is counted 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 are counted.

C. Evaluation Visits

The 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 *or allowed practitioner's* plan of care, the visit would become the first billable visit in the 30-day period.

The Medicare contractor will cover an observation and evaluation (or reevaluation) visit made by a nurse (see §40.1.2.1 for a further discussion of skilled nursing observation and evaluation visits) or other appropriate personnel, ordered by the physician *or allowed practitioner* for the purpose of evaluating the patient's condition and continuing need for skilled services, 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 an administrative function, not a skilled visit.

80.10 *Telecommunications Technology*

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Telecommunications technology (other than audio-only telephone calls) can include: remote patient monitoring, defined as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency; teletypewriter (TTY) technology; and 2-way audio-video telecommunications technology that allows for real-time interaction between the patient and clinician. Telecommunications technology can be ordered as part of a home health plan of care but such services cannot be reported as a visit without the provision of another skilled service. If telecommunications technologies are used by the home health agency, the costs of any equipment, set-up, and service related to the technology are allowable only as administrative costs. Visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the technology, without the provision of a skilled service, are not separately billable. However, HHAs may include the costs of telecommunications technology as an allowable administrative cost (that is, operating expense), if the technology is used by the HHA to augment the care planning process.

90 - Medical and Other Health Services Furnished by Home Health Agencies

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Payment may be made by Medicare contractors to a home health agency which 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 and payment rules other than when a home health plan of care is in effect.

1. 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;

2. Prosthetic (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);

3. Leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes and adjustments to these items when ordered by a physician *or allowed practitioner*. (See Pub 100-02, Medicare Benefit Policy Manual, Chapter 15);

4. Outpatient physical therapy, outpatient occupational therapy, and outpatient speech-language pathology services (for a patient not under a home health plan of care). (See Pub 100-02, Medicare Benefit Policy Manual, Chapter 15); and

5. Rental and purchase of durable medical equipment. (See Pub 100-02, Medicare Benefit Policy Manual, Chapter 15.) If a beneficiary meets all of the criteria for coverage of home health services and the HHA is providing home health care under the Hospital Insurance Program (Part A), any DME provided and billed to the Medicare contractor 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.

6. Ambulance service. (See Pub 100-02, Medicare Benefit Policy Manual, Chapter 10, Ambulance Services)

7. Hepatitis B Vaccine. Hepatitis B vaccine and its administration are covered under Part B for patients who are at high or intermediate risk of contracting hepatitis B. 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 a hepatitis B virus carrier, homosexual men, illicit injectable drug users. 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. 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. The vaccine may be administered, upon the order of a doctor of medicine or osteopathy, by home health agencies.

8. 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.

9. Pneumococcal and influenza vaccines. See Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §50.4.2 “Immunizations.”

10. Splints, casts. See Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services."

11. Antigens. See Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services."

100 - Physician *or Allowed Practitioner* Certification for Medical and Other Health Services Furnished by Home Health Agency (HHA)

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

A physician *or allowed practitioner* must certify that the medical and other health services covered by medical insurance, which were provided by (or under arrangements made by) the HHA, were medically required. This certification needs to be made only once where the patient may require over a period of time the furnishing of the same item or service related to one diagnosis. There is no requirement that the certification be entered on any specific form or handled in any specific way as long as the approach adopted by the HHA permits the Medicare contractor to determine that the certification requirement is, in fact, met. A written physician *or allowed practitioner's* order designating the services required would also be an acceptable certification.

110 - Use of Telehealth in Delivery of Home Health Services

(Rev. 10438, Issued: 11-06-20, Effective: 03-01-20, Implementation: 01- 11-21)

Section 1895(e) governs the home health prospective payment system (PPS) and provides that telehealth services are outside the scope of the Medicare home health benefit and home health PPS.

This provision does not provide coverage or payment for Medicare home health services provided via a telecommunications system. The law does not permit the substitution or use of a telecommunications system to provide any covered home health services paid under the home health PPS, or any covered home health service paid outside of the home health PPS. As stated in 42 CFR 409.48(c), a visit is an episode of personal contact with the beneficiary by staff of the home health agency (HHA), or others under arrangements with the HHA for the purposes of providing a covered service. The provision clarifies that there is nothing to preclude an HHA from adopting telemedicine or other technologies that they believe promote efficiencies, but there is no separate reimbursement for those technologies under the Medicare home health benefit. *However, Medicare does recognize services furnished via telecommunications technology (see section 80.10) as an allowed administrative cost on Medicare cost reports if telecommunications technology is used by the HHA to augment the care planning process, and the technology is indicated on the plan of care.*

This provision does not waive the current statutory requirement for a physician *or allowed practitioner* certification of a home health plan of care under current §§1814(a)(2)(C) or 1835(a)(2)(A) of the Act.