



Home Health Conditions of Participation (CoPs): Final Rule

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About HEALTHCAREfirst

- Industry leader in Web-based EHR software, coding & billing services, CAHPS survey administration, and advanced analytics for home health and hospice:
 - Founded in 1992
 - Headquartered in Springfield, MO with additional office in Louisville, KY
 - One of the fastest growing providers of our kind
 - More than 4,000 home health and hospice agencies nationwide
- We enable our customers to:
 - Make timely and accurate decisions for excellent patient care
 - Adapt quickly to changing requirements and needs
 - Automate agency functions quickly and with high value.

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EHR Software and Beyond



SOFTWARE

- Web-based Agency Management Software for home health and hospice agencies
- DDE Connectivity
- All Payer Eligibility Verification
- Physician Portal
- OASIS Scrubber

SERVICES

- Coding
- OASIS Review
- Billing
- CMS Submission of Hospice Item Set Data

ANALYTICS powered by DEYTA

- Executive, Clinical, and Financial KPIs
- Market Insights to grow referrals
- Robust QAPI management and benchmarking
- Hospice CAHPS and HHCAHPS

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- Strengthen Profitability
- Ensure Compliance
- Improve Quality



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- Updated CoP: Condition Titles and Organization
- Specific CoP Revisions and Additions
 - General Provisions
 - Patient Care
 - Organizational Environment
- Next Steps for HHAs

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Overarching Goal

- Obtaining quality health care that promotes high quality patient care at all times for all patients
- Focus
 - Patient-centered
 - Data-driven
 - Outcome-oriented process
- Requires
 - Taking advantage of continuing advances in the health care delivery field

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Cautions

- Enforcement date: July 13, 2017
 - Exception: QAPI improvement January 13, 2018
- Caveat: CMS may yet
 - Rescind rule
 - Delay effective date
- Remember: Home Health CoP
 - Apply to ALL HHA patients
 - State licensure regulations remain in effect (most stringent rule applies)
- Final Rule:
- <https://www.federalregister.gov/documents/2017/01/13/2017-00283/medicare-and-medicaid-program-conditions-of-participation-for-home-health-agencies>.
- Email box for questions: newhhacops@cms.hhs.gov

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Subparts and Conditions

- **Subpart A—General Provisions**
 - 484.1 Basis and scope.
 - 484.2 Definitions.
- **Subpart B--Patient Care**
 - 484.40 Condition of participation: Release of patient identifiable OASIS information
 - 484.45 Condition of participation: Reporting OASIS information
 - 484.50 Condition of participation: Patient rights
 - 484.55 Condition of participation: Comprehensive assessment of patients
 - 484.60 Condition of participation: Care planning, coordination of services, and quality of care
 - 484.65 Condition of participation: Quality assessment and performance improvement
 - 484.70 Condition of participation: Infection prevention and control
 - 484.75 Condition of participation: Skilled professional services
 - 484.80 Condition of participation: Home health aide services

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Subparts and Conditions

- **Subpart C--Organizational Environment**
 - 484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients
 - 484.102 Condition of participation: Emergency preparedness
 - 484.105 Condition of participation: Organization and administration of services
 - 484.110 Condition of participation: Clinical records.
 - 484.115 Condition of participation: Personnel qualifications

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§484.2 Definitions

- **Removed**
 - Nonprofit home health agency
 - Progress Note
 - Subunit
 - Supervision

(Note: Summary note not removed, but no longer required)
- **Redefined**
 - Parent
 - Deleted reference to subunit
 - Primary Home Health Agency
 - HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable)

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§484.2 Definitions

- **Redefined**
 - Branch Office
 - Removed “Sufficiently close
 - Added parent home health agency must provide supervision and administrative control of any branch office
 - Clinical note
 - Added: “timed” (contact with a patient that is written, timed, and dated)
 - Added: during a given period of time.
 - Timed means: time that order received or a service provided
 - Proactively record the time of day that each verbal order is received
 - Requires all entries in the clinical record to be timed

(Note: Does not require physician signature to be timed)

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§484.2 Definitions

- **Added**
 - In advance
 - HHA staff must complete the task prior to performing any hands-on care or any patient education
 - Quality indicator
 - Specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care
 - Representative
 - Patient's legal representative, such as a guardian, who makes healthcare decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

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§484.2 Definitions

- **Added**
 - Verbal order
 - Physician order
 - Spoken to appropriate personnel and
 - Later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.
 - Supervised practical training
 - Training in a practicum laboratory or other setting
 - Trainee demonstrates knowledge while providing covered services to an individual
 - Under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse

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§484.45 Condition of Participation: Reporting OASIS Information

- Transmit test data to the **QIES ASAP System or CMS OASIS contractor**
- Transmit data using electronic communications **software that complies with the Federal Information Processing Standard**

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§484.50 Condition of Participation: Patient Rights

- Right to be informed **in a language and manner the individual understands**
- **Standard: Notice of Rights**
 - **Provide verbal notice of rights and responsibilities**
 - **No later than end of second professional visit**
 - **In primary or preferred language, understandable manner**
 - **Free of charge, with the use of a competent interpreter**
 - **Provide written notice of rights and responsibilities**
 - **In advance of care**
 - **Patient and the patient's legal representative**
 - **Unless: patient-selected representative within 4 business days of the initial evaluation visit)**
 - **Written, understandable to those with limited English proficiency and individuals with disabilities**
 - **Including transfer and discharge policies**
 - **Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints**
 - **An OASIS privacy notice to all patients for whom the OASIS data is collected.**
 - **Obtain the patient's or legal representative's signature confirm receipt**

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§484.50 Condition of Participation: Patient Rights

- Standard: Exercise of rights
 - Patient
 - **Court appointed “legal” representative (to extent determined by court)**
 - **Patient self-selected representative (as patient chooses)**

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§484.50 Condition of Participation: Patient Rights

- Standard: Rights of the patient
 - Have property and person treated with respect
 - **Be free: verbal, mental, sexual, and physical abuse, injuries unknown source, neglect, property misuse**
 - Make complaints to the HHA
 - **Participate in, be informed about, and consent or refuse throughout**
 - Completion of all assessments
 - Care to be furnished
 - Establishing and revising the plan of care
 - The disciplines that will furnish the care
 - The frequency of visits
 - Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;
 - Any factors that could impact treatment effectiveness; and
 - Any changes in the care to be furnished
 - Receive all services outlined in the plan of care.
 - Confidential clinical record and access to or release of patient information and clinical records
 - **Payment information as soon as possible in advance of next visit (before services furnished)**

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§484.50 Condition of Participation: Patient Rights

- Receive proper **written notice in advance of a specific service, if service may be non-covered care; in advance of reducing or terminating on-going care (BNI)**
- State toll free home health telephone hot line purpose and contact information
- **Be advised of the names, addresses, and telephone numbers of Federal/State**
 - Agency on Aging
 - Center for Independent Living
 - Protection and Advocacy Agency
 - Aging and Disability Resource Center
 - Quality Improvement Organization
- Be free from any discrimination or reprisal for exercising rights
- **Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services**

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§484.50 Condition of Participation: Patient Rights

- **Standard: Transfer and discharge**
 - **The right to be informed of the HHA's policies for transfer and discharge**
 - **May only transfer or discharge the patient from the HHA if:**
 - **For patient's welfare, HHA and responsible physician agree that HHA can no longer meet the patient's needs, based on the patient's acuity**
 - Must arrange a safe and appropriate transfer to other care entities
 - **The patient or payer will no longer pay for the services**
 - **Responsible physician and HHA agree that the measurable outcomes/goals and services no long needed**
 - **The patient refuses services, elects to be transferred or discharged;**
 - **Under a policy set by the HHA for the purpose of addressing discharge for cause: disruptive, abusive, or uncooperative behavior that interferes with ability to provide care/operate effectively after:**
 - Advise patient, representative, the physician(s) post discharge caregivers of discharge
 - Make efforts to resolve the problem(s)
 - Provide contact information for other agencies or providers
 - Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;
 - **Patient death**
 - **HHA ceases to operate**

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§484.50 Condition of Participation: Patient Rights

- **Standard Investigation of complaints: The HHA must**
 - Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics:
 - Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately; and
 - **Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA**
 - Document both the existence of the complaint and the resolution of the complaint; and
 - **Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.**
 - **Any HHA staff (employed & contract) seeing incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property must report these findings immediately to the HHA and other appropriate authorities in accordance with state law**

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§484.50 Condition of Participation: Patient Rights

- **Standard: Accessibility**
 - **Information must be provided to patients in plain language and in a manner that is accessible and timely to:**
 - **Persons with disabilities, including accessible web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.**
 - **Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations**

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§484.55 Condition of Participation: Comprehensive Assessment of Patients

- A registered nurse must conduct an initial assessment visit unless therapy only
- The patient's current health, **psychosocial**, functional, and **cognitive status**;
- The **patient's strengths, goals, and care preferences**
- Information that may be used to demonstrate the patient's progress toward achievement of the goals identified by:
 - **Patient**
 - **Measurable outcomes identified by the HHA**
- **The patient's continuing need for home care**
- The patient's medical, nursing, rehabilitative, social, and discharge planning needs
- **A review of all medications the patient is currently using**
- **Primary caregiver(s), if any, and other available supports**
 - **Willingness and ability to provide care, and**
 - **Availability and schedules**
- **The patient's representative (if any)**
- **Incorporation** of current version of the Outcome and Assessment Information Set (OASIS) items

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§484.55 Condition of Participation: Comprehensive Assessment of Patients

- Standard: Update of the comprehensive assessment
 - Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, **or on physician-ordered resumption date**

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§484.60 Condition of Participation: Care Planning, Coordination, and Quality of Care

- **Standard Plan of Care:**
 - **Each patient must receive an individualized written plan of care, including any revisions or additions**
 - **Plan of care must include (and patient receive)**
 - **Care and services necessary to meet the patient-specific needs**
 - **Responsible discipline(s)**
 - **Patient-specific measurable outcomes**
 - **Patient and caregiver education and training**
 - **Established, periodically reviewed, signed by a doctor of medicine, osteopathy, or podiatry**
 - **Policy: Must be reviewed and signed by the physician responsible for plan of care**

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§484.60 Condition of Participation: Care Planning, Coordination, and Quality of Care

All pertinent diagnoses;
The patient's mental, **psychosocial, and cognitive status**;
The types of services, supplies, and equipment required;
The frequency and duration of visits to be made;
Prognosis;
Rehabilitation potential;
Functional limitations;
Activities permitted;
Nutritional requirements;
All medications and treatments;
Safety measures to protect against injury;

- **A description of the patient's risk for emergency department visits and hospital re-admission**
- **Patient-specific interventions to address the underlying risk factors**
- **Patient and caregiver education and training to facilitate timely discharge**
- **Patient-specific interventions and education**
- **Measurable outcomes and goals identified by the HHA and the patient**
- **Information related to any advanced directives**
- **Any additional items the HHA or physician may choose to include**
- **All patient care orders, including verbal orders, must be recorded in the plan of care**

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§484.60 Condition of Participation: Care Planning, Coordination, and Quality of Care

- **Standard: Conformance with physician orders**
 - In accord with law and agency policy
 - Drugs, services, and treatments are administered only as ordered by a physician
 - Influenza and pneumococcal vaccines per agency policy after assessment
 - Verbal orders must be
 - Accepted by authorized personnel
 - Documented, signed, dated, **timed (time received)**
 - By nurse/other qualified practitioner responsible for furnishing or supervising the ordered services
 - **Authenticated** and dated by the physician
 - **HHA must promptly alert all relevant physician(s) to any changes in patient's condition or needs that suggest that outcomes are not being achieved and/or plan of care should be altered**

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§484.60 Condition of Participation: Care Planning, Coordination, and Quality of Care

- **A revised plan of care must reflect**
 - **Current information from the patient's updated comprehensive assessment**
 - **Information concerning the patient's progress toward the measurable outcomes and goals**
- **Revisions to the plan of care must be communicated to:**
 - **Patient, representative (if any), caregiver, and all physicians issuing orders for the HHA plan of care**
- **Revisions to patient's discharge must be communicated to:**
 - **Patient, representative, caregiver, all physicians issuing orders for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible after discharge**

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§484.60 Condition of Participation: Care Planning, Coordination, and Quality of Care

- **Standard: Coordination of care.** The HHA must:
 - **Assure communication with all physicians involved in the plan of care**
 - **Integrate orders from all physicians involved in the plan of care**
 - **Integrate services (directly or under arrangement)**
 - Identify needs and factors that could affect patient safety and treatment effectiveness
 - Coordination of care by all disciplines
 - **Coordinate care delivery to meet the patient's needs**
 - Involve patient, representative (if any), and caregiver(s) in coordination activities
 - **Ensure patient, caregiver(s), receive ongoing education and training**
 - **Provide training to ensure timely discharge**

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§484.60 Condition of Participation: Care Planning, Coordination, and Quality of Care

- **Standard: Written information to the patient**
 - **The HHA must provide the patient and caregiver with a copy of written instructions outlining:**
 - Visit schedule
 - Frequency of visits
 - Patient medication schedule/instructions: name, dosage, frequency, including medications will be administered by HHA
 - Any treatments, including therapy services.
 - Any other pertinent instruction
 - Name and contact information of the HHA clinical manager

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§484.65 Condition of Participation: Quality Assessment, Performance Improvement

- **Standard: Develop, implement, evaluate, and maintain QAPI program**
 - **Oversight by governing body to ensure that the program**
 - Reflects the complexity of its organization and services
 - Involves all HHA services (including contracted)
 - Focuses on indicators related to improved outcomes
 - Include use of emergent care services
 - Include hospital admissions and re-admissions
 - Takes actions that address the HHA's performance including
 - Prevention and
 - Reduction of medical errors
 - **Maintain documentary evidence of QAPI program**
 - **Be able to demonstrate its operation to CMS**

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§484.65 Condition of Participation: Quality Assessment, Performance Improvement

- **Standard: Program scope**
 - **Identification of indicators that:**
 - Will improve health outcomes, patient safety, and quality of care
 - Capable of showing measurable improvement in indicators
 - Measure, analyze, and track quality indicators
 - Include adverse patient events
 - Include aspects of performance that enable assessment of processes of care, services, and operations

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§484.65 Condition of Participation: Quality Assessment, Performance Improvement

- **Standard: Program data**
 - **The program must utilize quality indicator data:**
 - Include measures derived from OASIS
 - Other relevant data
 - **The HHA must use the data to:**
 - Monitor the effectiveness and safety of services and quality of care
 - Identify opportunities for improvement
 - **Obtain governing body approval of frequency and detail of data**

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§484.65 Condition of Participation: Quality Assessment, Performance Improvement

- **Standard: Program activities**
 - **Performance improvement activities:**
 - Focus on high risk, high volume, or problem-prone areas
 - Consider incidence, prevalence, and severity of problems
 - Lead to an immediate of correction problems that do/have potential to threaten the health and safety of patients (immediate jeopardy)
 - Track adverse patient events
 - Analyze their causes
 - Implement preventive actions
 - **Take actions aimed at performance improvement**
 - **Measure success and track performance**
 - Ensure that improvements are sustained

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§484.65 Condition of Participation: Quality Assessment, Performance Improvement

- **Standard: Performance improvement projects by January 13, 2018**
 - Conduct performance improvement projects
 - Determine number and scope conducted annually based on
 - Scope
 - Complexity
 - Past performance
 - Document
 - Projects undertaken
 - Reasons for conducting projects
 - Measurable progress achieved

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§484.65 Condition of Participation: Quality Assessment, Performance Improvement

- **Standard: Executive responsibilities**
- **Governing body**
 - Defines implements, and maintains
 - Ongoing program for quality improvement and patient safety
 - Addresses
 - Priorities
 - Evaluation of improvement actions for effectiveness
 - Establishment, implementation, maintenance of clear expectations for patient safety
 - **Findings of fraud or waste are appropriately addressed**

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§484.70 Condition of Participation: Infection Prevention and Control

- **The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.**
- **Standard: Prevention**
 - Follow accepted standards of practice to prevent the transmission of infections and communicable diseases.
- **Standard: Control**
 - Maintain a coordinated agency-wide program
 - Surveillance
 - Identification
 - Prevention
 - Control
 - Investigation of infectious and communicable diseases
 - Include in infection control program
 - Method for identifying infectious and communicable disease problems
 - Plan for the appropriate actions for improvement and disease prevention
- **Standard: Education**
 - Provide infection control education to staff, patients, and caregiver(s)

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§484.75 Condition of Participation: Skilled Professional Services

- **Directly or under arrangement**
 - Skilled nursing services,
 - Physical therapy
 - Speech-language pathology services
 - Occupational therapy
 - Physician
 - Medical social work services
- **Skilled professionals who provide services must participate in the coordination of care**
- **Standard: Provision of services by skilled professionals**
 - Authorized, delivered, and supervised
 - By health care professionals meeting qualifications at §484.115
 - In accord with HHA's policies and procedures

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§484.75 Condition of Participation: Skilled Professional Services

- **Standard: Responsibilities of skilled professionals**
 - Ongoing interdisciplinary assessment of patient
 - Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s)
 - Providing services ordered by the physician in the plan of care;
 - Patient, caregiver, and family counseling
 - Patient and caregiver education
 - Preparing clinical notes
 - Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care
 - Participation in the HHA's QAPI program
 - **Participation in HHA-sponsored in-service training**

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§484.75 Condition of Participation: Skilled Professional Services

- **Supervision of skilled professional assistants**
 - Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).
 - Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(f) or (h), respectively.
 - Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m)

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§484.80 Condition of Participation: Home Health Aide Services

- Standard: Home health aide qualifications (by employee or contract)
 - Specified training and competency evaluation program; or
 - Specified competency evaluation program; or
 - **Nurse aide training and competency evaluation program approved by the state as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the state nurse aide registry; or**
 - The requirements of a state licensure program that meets the training and competency evaluation provisions
- HHA must maintain documentation to demonstrate requirements met

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§484.80 Condition of Participation: Home Health Aide Services

- A home health aide training program must address:
 - **Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff**
 - Observation, reporting, and documentation of patient status and the care or service furnished
 - Reading and recording temperature, pulse, and respiration
 - Basic infection prevention and control procedures
 - Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor
 - Maintenance of a clean, safe, and healthy environment
 - Recognizing emergencies and the knowledge of instituting emergency procedures and their application
 - The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property

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§484.80 Condition of Participation: Home Health Aide Services

- A home health aide training program must address:
 - Appropriate and safe techniques in performing personal hygiene and grooming tasks that include:
 - Bed bath
 - Sponge, tub, and shower bath
 - Hair shampooing in sink, tub, and bed
 - Nail and skin care
 - Oral hygiene
 - Toileting and elimination
 - Safe transfer techniques and ambulation
 - Normal range of motion and positioning
 - Adequate nutrition and fluid intake
 - **Recognizing and reporting changes in skin condition**
 - Any other task that HHA may choose **as permitted under state law**

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§484.80 Condition of Participation: Home Health Aide Services

- **Standard: Competency Evaluation**
 - Must be evaluated by observing an **aide's performance with a patient**
 - Personal hygiene and grooming tasks that include
 - Bed bath;
 - Sponge, tub, and shower bath;
 - Hair shampooing in sink, tub, and bed;
 - Nail and skin care;
 - Oral hygiene;
 - Toileting and elimination;
 - Safe transfer techniques and ambulation;
 - Normal range of motion and positioning
 - The remaining subject areas evaluated through written examination, oral examination, or after observation of a home health aide with a patient

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§484.80 Condition of Participation: Home Health Aide Services

- A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section
 - **By a registered nurse in consultation with other skilled professionals**
- A home health aide is not considered competent in any task evaluated as unsatisfactory
 - Must not perform that task without direct supervision by a registered nurse until evaluated satisfactory
- Is not considered to have successfully passed a competency evaluation if the aide has an “unsatisfactory” rating in more than one of the required areas

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§484.80 Condition of Participation: Home Health Aide Services

- Standard: In-service training
 - At least 12 hours of in-service training during each 12-month period
 - HHA must maintain documentation
 - May occur while an aide is furnishing care to a patient.
 - **In-service training may be offered by any organization and must be supervised by a registered nurse**
- Standard: Qualifications for instructors conducting classroom and supervised practical training
 - **Registered nurse**
 - **Minimum of 2 years nursing experience, at least 1 year of which must be in home health care**
 - **Or, by other individuals under the general supervision of the registered nurse**

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§484.80 Condition of Participation: Home Health Aide Services

- Standard: Eligible training and competency evaluation organizations.
- By any organization except by an HHA that, within the previous 2 years:
 - Was out of compliance with the requirements of paragraphs training and competency requirements
 - Subjected to an extended (or partially extended) survey as a result of substandard care
 - Assessed a civil monetary penalty of \$5,000 or more as an intermediate sanction; or
 - Found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed to oversee the management
 - Had all or part of its Medicare payments suspended; or
 - Found under any federal or state law to have:
 - Participation in the Medicare program terminated; or
 - Assessed a penalty of \$5,000 or more for deficiencies in federal or state standards for HHAs; or
 - Subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or
 - Operated under temporary management that was appointed to oversee the operation of the HHA Been closed, or had its patients transferred by the state; or
 - **Been excluded from participating in federal health care programs or debarred from participating in any government program**

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§484.80 Condition of Participation: Home Health Aide Services

- Standard: Home health aide assignments and duties
- **Assigned by registered nurse or other appropriate skilled professional**
- **Written patient care instructions prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist)**
- A home health aide provides services:
 - Ordered by the physician
 - Included in the plan of care
 - Permitted to be performed under state law
 - **Consistent with the home health aide training**

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§484.80 Condition of Participation: Home Health Aide Services

- If receiving skilled services
 - On-site visit to home
 - **By RN or other appropriate skilled professional familiar with the patient, plan of care, and written patient care instructions**
 - **No less frequently than every 14 days**
 - Home health aide does not have to be present during this visit
- If no skilled services
 - On-site visit where the patient is receiving care
 - By RN
 - No less frequently than every 60 days
 - To observe and assess each aide while s/he is performing care

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§484.80 Condition of Participation: Home Health Aide Services

- **Area of concern noted in aide services**
 - **Supervising individual must make an on-site visit to location where patient is receiving care**
 - **Observe and assess the aide while performing care**
- **RN or appropriate skilled professional must**
 - **Make an annual on-site visit to the location where a patient is receiving care**
 - **Observe and assess each aide while he or she is performing care**
- **If a deficiency in aide services is verified during an on-site visit**
 - **HHA must conduct, and the home health aide must complete a competency evaluation**

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§484.80 Condition of Participation: Home Health Aide Services

- **Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:**
 - Following the patient’s plan of care for completion of tasks assigned
 - Maintaining an open communication process with patient, representative, caregivers, and family
 - Demonstrating competency with assigned tasks
 - Complying with infection prevention and control policies and procedures
 - Reporting changes in the patient’s condition
 - Honoring patient rights

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§484.100 Condition of Participation: Compliance Federal, State, Local Laws/Regs

- Standard: Laboratory services
- HHA engaging in laboratory testing outside self-administering
 - Testing certification must be in compliance with FDA requirements
- **HHA may not substitute its equipment for a patient’s equipment when assisting with self-administered tests**

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§484.102 Condition of Participation: Emergency Preparedness

- **Must comply with all applicable Federal, State, and local emergency preparedness requirements**
 - **Establish and maintain an emergency preparedness program**
 - **Emergency Plan**
 - **Policies and Procedures**
 - **Communication Plan**
 - **Training and Testing**

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§484.105 Condition of Participation: Organization/Administration of Services

- **Standard: Governing body**
 - **Assumes full legal authority and responsibility for:**
 - **Overall management and operation**
 - **Provision of all home health services**
 - **Fiscal operations**
 - **Review of agency's budget, operational plans**
 - **Quality assessment and performance improvement program**

(Note: Removed Group of Professionals/PAC)

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§484.105 Condition of Participation: Organization/Administration of Services

- Standard: Parent-branch relationship
 - **Parent responsible for**
 - **Reporting each branch to SA at time of survey and each time parent proposes to add or delete branch**
 - **Providing direct support and administrative control over branch**

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§484.105 Condition of Participation: Organization/Administration of Services

- **Services Under Arrangement**
 - Maintain responsibility for services
 - Written agreement
 - **Agency, organization, or individual providing services under arrangement may not have been:**
 - **Denied Medicare or Medicaid enrollment;**
 - **Been excluded or terminated from any federal health care program or**
 - **When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section**
 - **Had its Medicare or Medicaid billing privileges revoked; or**
 - **Been debarred from participating in any government program**
 - The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients

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§484.115 Condition of Participation: Personnel Qualifications

- Standard: Administrator
 - Appointed by and reports to governing body
 - Responsible for all day-to-day operations of the HHA
 - **Ensures that a clinical manager is available during all operating hours**
 - **Ensures**
 - HHA employs qualified personnel
 - Development of personnel qualifications and policies
 - **Is (or pre-designated person) available during all operating hours**
 - **Pre-designated person who acts when administrator no available**
 - Is qualified
 - Authorized in writing by administrator and governing body
 - Assumes responsibilities and obligations of administrator
 - May be the clinical manager

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§484.115 Condition of Participation: Personnel Qualifications

- Standard: Administrator
 - For individuals that began employment with the HHA prior to July 13, 2017, a person who:
 - Is a licensed physician;
 - Is a registered nurse; or
 - Has training and experience in health service administration and at least 1 year of supervisory administrative experience in home health care or a related health care program.
 - **For individuals that begin employment with an HHA on or after July 13, 2017, a person who:**
 - **Is a licensed physician, a registered nurse, or holds an undergraduate degree; and**
 - **Has experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program**

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§484.115 Condition of Participation: Personnel Qualifications

- **Clinical manager**
 - One or more qualified individuals
 - Provide oversight of all patient care services and personnel
 - Oversight must include the following
 - Making patient and personnel assignments
 - Coordinating patient care
 - Coordinating referrals
 - Assuring that patient needs are continually assessed
 - Assuring the development, implementation, and updates of the individualized plan of care

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§484.115 Condition of Participation: Personnel Qualifications

- **Standard: Clinical manager**
 - A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse
(Note: Eliminated supervising physician or nurse)

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§484.110 Condition of Participation: Clinical Records

- The HHA must maintain a clinical record
 - **Containing past and current information**
 - **Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice**
 - **Be available to the physician(s) issuing orders for the home health plan of care, and appropriate HHA staff**
 - May be maintained electronically

(Note: Deleted Summary Report and Progress Note)

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§484.110 Condition of Participation: Clinical Records

- **Standard: Contents of clinical record.** The record must include:
 - The patient's current comprehensive assessment, **including all of the assessments from the most recent home health admission**, clinical notes, plans of care, and physician orders
 - All interventions, including medication administration, treatments, and services, **and responses to those interventions**
 - Goals in the patient's plans of care and progress toward achieving them
 - **Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s)**
 - **Contact information for the primary care practitioner or other health care professional responsible care and services after discharge**

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§484.110 Condition of Participation: Clinical Records

- **A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible after discharge**
 - Within 5 business days of the patient’s discharge; or
 - A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient’s care will be immediately continued in a health care facility; or
 - A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer
- (Note: Required content to be determined in a separate rule)**

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§484.110 Condition of Participation: Clinical Records

- **Standard: Authentication.** All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry
- **Standard: Clinical records must be retained until 5 years after discharge**
- **Standard: Retrieval of clinical records.** A patient’s clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first)

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Action Steps

- Read the Rule (end of notice)
- Read the “Responses” to identify policy positions
- Watch for CMS release of Interpretive Guidance
- Identify regulations that require action by your HHA
 - Amend job descriptions, qualifications and duties
 - Create/amend policies, procedures, forms, and processes
 - Patient rights
 - Care plan processes
 - Patient written care information
 - Aide training
 - Create/conduct professional and home health aide in-service
 - QAPI Program
 - Infection control Program
 - Educate employees and contractors

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Are We Ready??



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Addendum: 2017 Changes to Current CoP

Current CoP	2017 CoP
§484.10, Patient rights	§484.50, Patient rights
§484.10(a)	Revised at §484.50(a)
§484.10(b)	Revised at §§484.50(b), (c), and (e)
§484.10(c)	Revised at §484.50 (c)
§484.10(d)	Revised at §484.50(c)
§484.10(e)	Revised at §484.50(c)
§484.10(f)	Revised at §484.50(c)
	New standard at §484.50(d), Transfer and discharge
	New standard at §484.50(e), Investigation of complaints

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Addendum: 2017 Changes to Current CoP

§484.11, Release of patient identifiable OASIS information	§484.40, Release of patient identifiable OASIS information
§484.12, Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles	§484.100, Compliance with Federal, State, and local laws and regulations related to the health and safety of patients
§484.12(a)	Revised at §484.100 and §484.100(b)
§484.12(b)	Redesignated at §484.100(a)
§484.12(c)	Revised at §484.60, §484.70, and §484.105(f)

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Addendum: 2017 Changes to Current CoP

§484.14(a)	Revised at §484.105(f)
§484.14(b)	Revised at §484.105(a)
§484.14(c)	Revised at §484.105(b)
§484.14(d)	Revised at §484.105(b), and §484.105(c)
§484.14(e)	Revised at §484.75(b) and §484.115
§484.14(f)	Revised at §484.105(e)
§484.14(g)	Revised at §484.60(d) and §484.105(c)
§484.14(h)	Revised at §484.105(e)
§484.14(i)	Revised at §484.105(h)
§484.14(j)	Revised at §484.100(c)

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Addendum: 2017 Changes to Current CoP

§484.16, Group of professional personnel	Deleted, see §484.65, Quality assessment and performance improvement (QAPI)
§484.18, Acceptance of patients, plan of care, and medical supervision	§484.60, Care planning, coordination of services, and quality of care
§484.18(a)	Revised at §484.60(a)
§484.18(b)	Revised at §484.60(c)
§484.18(c)	Revised at §484.60(b)
	New standard at §484.60(e), Written information to the patient
§484.20, Reporting OASIS information	§484.45, Reporting OASIS information
§484.30, Skilled nursing services	§484.75, Skilled professional services
§484.32, Therapy services	§484.75, Skilled professional services
§484.34, Medical social services	§484.75, Skilled professional services

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Addendum: 2017 Changes to Current CoP

§484.36, Home health aide services	§484.80, Home health aide services
§484.36(a)(1)	Revised at §484.80(b)
§484.36(a)(2)(i)	Revised at §484.80(f)
§484.36(a)(2)(ii)	Revised at §484.80(e)
§484.36(a)(3)	Revised at §484.80(b)
§484.36(b)(1)	Revised at §484.80(c)
§484.36(b)(2)(i)	Revised at §484.80(c)
§484.36(b)(2)(ii)	Revised at §484.80(h)
§484.36(b)(2)(iii)	Revised at §484.80(d)
§484.36(b)(3)(i)	Revised at §484.80(c) and (d)
§484.36(b)(3)(ii)	Revised at §484.80(c) and (d)
§484.36(b)(3)(iii)	Revised at §484.80(c)
§484.36(b)(4)	Revised at §484.80(c)
§484.36(b)(5)	Redesignated at §484.80(c)
§484.36(b)(6)	Deleted
§484.36(c)	Revised at §484.80(g)
§484.36(d)	Revised at §484.80(h)
§484.36(e)	Revised at §484.80(i)

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Addendum: 2017 Changes to Current CoP

§484.38, Qualifying to furnish outpatient physical therapy or speech pathology services	Revised at §484.105(g)
§484.48, Clinical records	§484.110, Clinical records
§484.48(a)	Revised at §484.110(c)
§484.48(b)	Revised at §484.110(d)
	New standard at §484.110(a), Contents of clinical record
	New standard at §484.110(b), Authentication
	New standard at §484.110(e), Retrieval of clinical records
§484.52, Evaluation of the agency's program	Deleted, see §484.65, Quality assessment and performance improvement and §484.70, Infection prevention and control
§484.55, Comprehensive assessment of patients	§484.55, Comprehensive assessment of patients

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