Home Health Conditions of Participation: What You Need to Know

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Overall Goal

• Changes directed toward
  – Improving patient-centered outcomes of care
  – Engaging the patient, family and physician in the care planning
  – Engaging patient, family and physician in care delivery processes
Overall Goal

- Designed to enable surveyors to look at outcomes of care
- Specify that each individual receive the care according to assessed needs
- Remove focus from services and processes that must be in place
- Find opportunities for monitoring and improvement

General Provisions

- Consolidation, reorganization, removal of Conditions and Standards
- Grouping of patient care rules, place forward,
- Grouping of Organization and Administration, follow
- Title changes
- Addition of definitions
While I can explain the meaning of life, I don’t dare try to explain how the Medicare system works.

42CFR 484 Home Health Services

Current
• 484.1 Basis and Scope
• 484.2 Definitions
• 484.4 Personnel Qualifications
• 484.10 Patient Rights
• 484.11 Release of OASIS
• 484.12 Compliance Laws, etc.
• 484.14 Organization, Services, etc.
• 484.14(g) Summary of care every 60 days
• 484.12(c) Comply professional standards principles
• 484.16 Group of Professional Personnel
• 484.18 Accept Patients, Plan of Care, Supervision

Proposed Rule
484.1
484.2
484.115
484.50
484.40
484.100
484.105

Removed
484.105(f)(2)

484.60
42CFR 484 Home Health Services

Current

• 484.18(a) Plan of Care
• 484.30 Skilled Nursing
• 484.32 Therapy Services
• 484.34 Medical Social Worker
• 484.38 Outpatient Therapy
• 484.52 Evaluation of Agency’s Program
• 484.36 Home Health Aide
• 484.48 Clinical Record
• 484.55 Comprehensive Assessment
• New QAPI
• New Infection Control

Proposed Rule

484.60
484.75 Combined
484.75 Combined
484.75 Combined
484.105(g)
Removed
484.80
484.110
484.55
484.65
484.70

484.2 Definitions

• Bylaws: removed
• Branch Office
  – Must provide supervision and administrative control
  – Eliminated “sufficiently close”
  – Retain within geographic area of parent
• Clinical notes: added “timed” and changes during “given period of time”
• Quality indicator
  – Specific, valid, reliable measure of access, care outcomes, or satisfaction or measure of process of care
• Representative
  – Patient’s legal guardian or other person who participates in decisions related to patient care or well-being
• Issue: Need to differentiate between caregiver and representative
484.2 Definitions

- Nonprofit removed
- Parent, Primary, Proprietary, Public Subdivision unchanged
- Subunit
  - Eliminated
- Summary Report
  - Definition retained but not mentioned in regulation
- Supervision removed, replaced with “supervised practical training” under supervision of RN in lab or to patient.
- Verbal order
  - Physician order spoken to appropriate personnel and later put in writing for purpose of documenting, establishing or revising plan of care

Format

- Significant changes and additions
  - BOLDED
484.40 Release of Patient OASIS

• HHA or Agent in accord with written contract
  – Ensure confidentiality of patient information
  – May not release OASIS information to the public

484.45 Reporting OASIS

• HHA must report all OASIS collected
  – Encode as determined by Secretary
  – Accurately reflect condition at time of assessment
  – Transmit data in the required format using
    • Using compliant electronic communications software
    • Using Branch number
    • In conformance with CMS electronic specs
484.50 Patient Rights

- Obtain signature of patient/representative confirming receipt of copy of notice of rights
  - Consider determination of competence when informing of rights to patient, representative, or court appointed person
- Patient must be informed of rights in understandable language and manner
  - During initial assessment visit
  - In advance of providing care
  - Orally and in writing
  - Written notice must be understandable if LEP, disabled
  - Verbal notice in language, manner preferred using competent interpreter at no charge
  - Must inform patients/representatives of availability of free auxiliary aides and interpretation services

484.50 Patient Rights

- Patient must
  - Receive OASIS Privacy Notice
  - Have property and person treated with respect
  - Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property
  - Be free from discrimination
  - Permitted to make complaints
  - Have confidential records
  - Be advised of self pay before care initiated
  - Be advised of payment by Federal funds

HEALTHCARE +first +patients before paperwork
484.50 Patient Rights

• Participate in/informed of/consent or refuse
  – Completion of comprehensive assessment
  – Establishing and revising plan of care
  – Receiving a copy of plan of care
    • Care to be furnished based on assessment
    • Disciplines to furnish care
    • Frequency of visits
    • Expected outcomes
    • Factors that may impact treatment effectiveness
    • Any changes in care to be furnished

484.50 Patient Rights

• Patient Must Receive
  • Administrator name, business address and phone
  • Names, addresses, and telephone numbers of pertinent, Federally-funded and State-funded, State and local consumer information, consumer protection, and advocacy agencies
  • Information about the right to access auxiliary aids and language services how to access these services
  • HHA’s policies for admission, transfer, and discharge in advance of care being furnished
484.50 Patient Rights

• Patient must
  – Receive all services outlined in the plan of care
    • Have a confidential clinical record
    • Have access to or release of patient information and clinical records
  – Receive written notice in advance of
    • Non-coverage
    • Service to be reduced or terminated

484.50 Patient Rights

• Transfer or Discharge Requirements
• Patient right to be informed
• May discharge only if:
  – Discharge necessary for the patient’s welfare
    • HHA and physician agree needs can no longer be met based on acuity
    • The HHA must ensure a safe and appropriate transfer. Needs exceed the HHA’s capabilities
  – Patient or payer will no longer pay for the services
  – Transfer or discharge because improved/stabilized and physician agree
  – Patient refuses services/elects to be transferred or discharged
  – For cause under a policy set by the HHA for discharge
    • Patient's/other (or other persons in the patient's home) behavior
    • Delivery of care or the HHA operation seriously impaired
    • Ability of the HHA to operate effectively is seriously impaired
• Before discharges for cause HHA must:
  – Advise the patient, representative (if any), the physician and the patient’s primary care practitioner
  – Make efforts to resolve the problem(s)
  – Provide the patient and representative with contact information for other agencies
  – Document the problem(s) and efforts made to resolve

• Investigation of complaints
  – Failure in care
  – Mistreatment, neglect, abuse
  – Document complaint and actions taken
  – Take steps to prevent violations during investigation

• Report of any (including injuries of unknown source) to HHA and authorities by all staff
484.55 Comprehensive Assessment

- Each patient must receive an initial assessment
  - Within 48 hours of referral or MD ordered SOC
  - By RN unless therapy only case
- To determine
  - Immediate care and support needs
  - Medicare eligibility, including homebound status

484.55 Comprehensive Assessment

- Each patient must receive patient specific comprehensive assessment
- Must include, at a minimum
  - Current health, psychosocial, functional, and cognitive status
  - Strengths, goals
  - Care preferences identified by the patient
  - Measurable outcomes identified by the HHA
  - Continuing need for home care
  - Medical, nursing, rehabilitative, social, and discharge planning needs
  - Review of all medications
  - Primary caregiver(s), if any, and other available supports
  - Representative (if any)
  - Outcome and Assessment Information Set (OASIS)
  - Data items collected at inpatient facility admission or discharge
484.55 Comprehensive Assessment

- Update of Comprehensive Assessment
  - As often as condition indicates due to major decline or improvement
  - Last 5 days of every 60 days of SOC unless
  - Beneficiary elected transfer
  - Significant change in condition
  - Discharge and return home during 60 day episode
  - Within 48 hours of 24 hour inpatient stay or “physician ordered ROC date”

484.60 Care Planning, Coordination, Quality of Care

- Acceptance of patients
  - Reasonable expectation needs can be met in home
- Plan of care must be provided/revised based on needs
  - Specify care and services necessary to meet patient specific needs as in comprehensive assessment
  - Disciplines
  - Patient specific measurable outcomes and goals
  - Specify patient and caregiver education and training HHA will provide
- Services must be provided in accord with standards of practice
Each patient must receive services in the individualized plan

Plan must be established by physician

Verbal orders must be accepted by personnel authorized to do so

– In accord with agency policy and state laws
– Must be entered into the record, signed, dated and timed by RN or qualified practitioner
– Authenticated and dated by the physician

Care Plan Content

– All pertinent diagnoses
– Patient’s mental, psycho-social and cognitive status
– Types of services, supplies, and equipment required
– Frequency and duration of visits to be made
– Prognosis
– Rehab potential
– Functional limitations
– Activities permitted
– Nutritional requirements
484.60 Care Planning, Coordination, Quality of Care

• Care Plan Content
  – Medications
  – Treatments
  – Safety measures to protect against injuries
  – Patient education and caregiver education and training
  – Patient-specific interventions, educations
  – Measurable outcomes and goals identified by HHA and patient
  – Information related to advance directives
  – Any additional information the HHA or physician may choose
  – All patient care orders, including verbal orders

484.60 Care Planning, Coordination, Quality of Care

• Plan of care content
  – If discharged from hospital
    • Include description of risk for ED or hospital re-admission (low, medium, high)
    • Interventions necessary to address risk factors
484.60 Care Planning, Coordination, Quality of Care

- Conformance with Physician Orders
  - Drugs, services, treatments only as ordered by MD responsible for plan of care
  - Influenza and Pneumonia vaccine per policy in consult with a physician after assessment for contraindications

484.60 Care Planning, Coordination, Quality of Care

- Review and Revision Plan of Care
  - Plan must be periodically reviewed and revised by physician responsible for plan of care
    - As frequently as patient condition requires
    - No less frequently than every 60 days
  - Physician must be notified of changes in patient condition or needs that suggest outcomes not being achieved and plan of care needs to be altered
  - Revised plan of care must reflect updated comprehensive assessment
  - Revisions to plan due to change in patient status must be communicated to patient, representative, caregiver, physician responsible for plan of care
  - Revisions to discharge plan communicated to patient, representative, caregiver, MD responsible for plan, or primary practitioner
• Coordination of Care
  – Integrates agency services to assure
    • Identification factors that could affect safety and treatment effectiveness
    • Coordination of care by all disciplines
    • Communication with physician
  – Coordinates to meet patient needs and
    • Involve patient, representative, caregiver
  – Ensures that patient/representative/caregiver receive
    • Ongoing education and training
    • Training “to ensure timely discharge”

• Discharge or Transfer Summary Content
  – Initial reason for referral to the HHA
  – Description of the patient’s clinical, mental, psychosocial, cognitive, and functional status at the start of care
  – All services provided by the HHA
  – Start and end dates of HHA care
  – Patient’s clinical, mental, psychosocial, cognitive, and functional status at time of discharge or transfer
  – Updated, reconciled list of meds at time of discharge/transfer
  – Recommendations for ongoing care
  – Patient’s current individualized plan of care
  – Additional documentation that will assist in post-discharge or transfer, continuity of care, or that is requested by the receiving practitioner or facility.
484.60 Care Planning, Coordination, Quality of Care

• Discharge or Transfer Summary Content
  – Patient’s plan of care including latest physician orders
  – Documentation to assist in post-discharge/transfer continuity of care or as requested

484.65 Quality Assessment & Performance Improvement (QAPI)

• A QAPI program must be
  – Developed
  – Implemented
  – Evaluated
  – Maintained
• QAPI program must be
  – Effective
  – Ongoing
  – Agency wide
  – Data driven
• **QAPI Content**
  – Improved patient outcome indicator focus
  – Including hospital admissions
  – Takes actions to address performance across spectrum of care
  – Includes prevention and reduction of medical errors

• **HHA must**
  – Have documentary evidence of program
  – Is able to demonstrate operation of program

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• **Program Scope**
  – Be capable of showing measurable improvement
  – Evidence that improvement indicators will improve health outcomes, patient safety, quality of care
  – Measure analyze and track quality indicators
    • Adverse events, others
484.65 Quality Assessment & Performance Improvement (QAPI)

- Program data in design of QAPI
  - Use quality indicator data (including OASIS and others)

- Must use data that
  - Monitors effectiveness
  - Identifies opportunities for improvement
  - Are approved by HHA governing body

484.65 Quality Assessment & Performance Improvement (QAPI)

- QAPI PI Activities must
  - Focus on high risk, high volume, problem prone areas
  - Consider incidence, prevalence, severity of programs
  - Lead to immediate correction if health/safety threatened
  - Track adverse patient events
    - Analyze cause
    - Implement preventative action
484.65 Quality Assessment & Performance Improvement (QAPI)

- **HHA must**
  - Take action aimed at performance improvement
  - Measure its success and track performance to insure sustainability
  - Embark on performance improvement projects (number based on agency size, etc.)
  - Document QI improvement projects
    - Reason for conduct
    - Measurable progress

484.65 Quality Assessment & Performance Improvement (QAPI)

- **Governing body responsible**
  - Program definition
  - Implementation
  - Maintenance
  - Evaluation of effectiveness
  - Findings of fraud appropriately addressed
484.70 Infection Control

- Maintain and document a program
- Goal: prevention & control of infections/communicable diseases
  - Prevention
    - Follow accepted standards of practice
  - Control (as integral part of QAPI)
    - Maintain coordinated program for infections/communicable disease
      - Surveillance
      - Identification
      - Prevention
      - Control
      - Investigation
  - Identify problems
  - Plan actions to prevent disease
  - Include infection control education to staff, patients, and caregiver(s)

484.75 Skilled Professional

- Duties/responsibilities of RN, PT, SLP OT combined under Skilled Professional
  - Ongoing interdisciplinary assessment
  - Development/evaluation of plan of care with patient, etc.
  - Service provision per plan of care
  - Patient etc. counseling and education
  - Preparation of clinical notes
  - Communication with physician, other health practitioners
  - Participation in QAPI
  - Participation in agency in-service
  - Supervision of assistants
484.80 Home Health Aides

- Training Unchanged
- Aide must observe, report and document patient status, care, services furnished
- May receive written instructions from any appropriate professional
- Professional who prepares instructions must be responsible for aide supervision
- Requires joint supervisory visits If deficient care identified during a 14 day supervisory visit
  - Requires new competency evaluation if deficient care found

484.80 Home Health Aides

- Supervision visits must address and ensure care in a safe and effective manner, including
  - Following the patient’s plan of care for completion of tasks assigned to a home
  - Maintaining an open communication process with the patient, representative, caregiver
  - Demonstrating competency with assigned tasks
  - Complying with infection prevention and control policies and procedures
  - Reporting changes in the patient’s condition
  - Honoring patient rights
484.100 Compliance with Federal, State, Local Laws

- Disclosure of ownership and management information: names and addresses owners, involved corporations, board, officers directors, managing employees, etc.
- Licensing: agency, branches, persons providing services licensed according to state
- Laboratory: in accord with FDA regulations by certified lab
  - HHA may not substitute its equipment for a patient’s equipment when assisting with self-administered tests except initially before patient obtains equipment.

484.105 Organization & Administration Services

- HHA must
  - Organize, manage, administer resources
  - Attain highest functional capacity, overcome patient deficits
  - Assure administrative and supervisory functions not delegated to another outside
  - Directly monitor and control all services
  - Set forth its organizational structure, lines of authority and services furnished

Note: Subunit removed
484.105 Organization & Administration Services

- Governing body assumes full legal authority and responsibility for
  - Overall management and operations
  - Provision of services
  - Fiscal operations
  - Review of budget and operational plans
  - QAPI

  **Note:** removed arrange professional advice and reviews bylaws

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484.105 Organization & Administration Services

- Administrator, who is appointed by governing body, must
  - Be responsible for day-to-day operations
  - Ensures a skilled professional is available during operating hours
  - Pre-designate a person authorized in writing by administrator and governing body to act in absence
  - Be available during all operating hours (or designee)

- 484.115 Personnel Qualifications
  - Administrator is a:
    - Licensed physician, or
    - Registered nurse, or
    - Person who holds undergraduate degree in Health service administration and has at least one year of which is in home health or related health care program
Clinical Manager

- Licensed physician or RN
- Responsible for oversight of services & personnel
  - Make 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
  - Assure development personnel qualifications, policies

Note: Eliminated “during all operating hours”

Clinical Manager

In response to a survey

Suppose we let you write all of our policies, design our forms, write all the plans of care and we have the supervising nurse shot. Would that be satisfactory?
• Parent-Branch Relationship
  – Parent is responsible for
    • Reporting branch locations at time of request initial survey, each survey, and time branch proposed/deleted
    • Parent provides direct support and administrative control of branches
    • See “Branch” in definitions

484.105 Organization & Administration Services

• The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.
• Services Under Arrangement requirements
  – Written agreement with another agency, with an organization, or with an individual
  – Maintain overall responsibility for the services and manner furnished
  – The 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 Medicaid
    • Had its Medicare or Medicaid billing privileges revoked; or
    • Been debarred from participating in any government program
484.105 Organization & Administration Services

• Services furnished
  – Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services)
    • Are made available on a visiting basis, in a place of residence used as a patient’s home
  – Direct services
    • Must provide at least one of the services in this section directly (removed qualifying)
    • May provide the second service and additional under arrangement

484.105 Organization & Administration Services

• Unchanged
  – Outpatient therapy
  – Institutional planning
    • Annual Operating budget
    • Capital expenditure plan
    • Preparation of plan and budget
    • Annual review of plan and budget
484.110 Clinical Record

- Patient record must
  - Contain past and current information
  - Be accurate, adhere to current clinical record documentation standards of practice
  - Be available to the physician who is responsible
  - for the home health plan of care and appropriate HHA staff
- May be maintained electronically

The record must include:
- Current comprehensive assessment
- All assessments from the most recent home health admission, clinical notes, plans of care
- Physician orders
- Interventions, medication administration, treatments, and services
- Responses to interventions
- Goals in the patient’s plans of care and the patient’s progress
- Contact information
  - Patient and applicable representative
  - Primary care practitioner
  - Other health care professional responsible after discharge
- Completed discharge or transfer summary which must be sent to physician, primary care practitioner, or inpatient facility
  - Within 7 calendar days, or, if to a facility within 2 calendar days of discharge or transfer
484.110 Clinical Record

- Clinical record content
  - Current comprehensive assessment
  - All of the assessments from the most recent home health admission
  - Clinical visit notes
  - Individualized plans of care
  - All interventions, including medication administration, treatments, services
  - Responses to interventions
  - Goals in the patient’s plan of care
  - Progress toward achieving the goals
  - Contact information for the patient and representative
  - Contact information for the primary care practitioner or other health care professional responsible after discharge
  - Discharge or transfer summary
    - Within 7 calendar days, or, if to a facility within 2 calendar days of discharge or transfer

484.110 Clinical Record

- Documentation Authentication
  - All entries must be
    - Legible, clear, complete
    - 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

- Authentication (as defined in preamble):
  - Process to identify person who made entry by signature and title or secured electronic identification attesting to accuracy and completeness
484.110 Clinical Record

• Retention of records
  – Must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.
  – HHA’s policies must provide for retention of clinical records even if it discontinues operation.
  – When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

484.110 Clinical Record

• Protection of records
  – Record and content must be safeguarded against loss or unauthorized use
  – HHA must be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164 (HIPAA)

• Retrieval of clinical records
  – Record (hard copy or electronic form) must be made available to a patient/authorized individual/entity upon request
Medicare, as a rule, will always expect you to know if the instructions you got from a Medicare representative were correct or incorrect.

When the enforcement officer calls, you will then learn whether you guessed right.