2017 Conditions of Participation

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Effective July 13, 2017

All provisions except for 1 QAPI standard will take effect July 13, 2017.
See slide (50) for one QAPI (484.65.d) that will not take effect until January 2018

Represents a major revision in several areas.

Agenda
- High level overview
- Deep dive into details
  - Definitions
  - Patient Rights
  - Comprehensive Assessment
  - Care Plan
  - Quality Assessment (QAPI)
  - Infection Control
  - Skilled Services
  - Home Health Aide
  - Organizational Environment
  - Clinical Record
  - Personnel Qualifications
High Level Overview

Changes

- Structural Changes
  - 3 Sections remain, but significant Renaming and Renumbering
    - 484.1 - 484.2 General Provisions
    - 484.40 - 484.80 Patient Care
    - 484.100 - 484.115 Organizational Environment
  - Combination of standards
- 2 new standards
  - 484.65 - Quality Assessment and Performance Improvement (QAPI)
  - 484.70 - Infection Control

Elimination of Standards

- 60 Day Summary to Physician
- Group of Professionals (PAC)
- Quarterly Record Review
- Subunit
  - Need to convert to branch by 7/13/17
Key changes

- Raises Governing body and Administrator involvement and accountability
- Creates Clinical Manager designation
- Expanded Patient Rights
- Increased focus on Care Coordination and Care Planning
- Expanded Assessment and Plan of Care Requirements
- Creates Summary and Time Frame requirements for Transfer and Discharge
- Changes Supervision and Training requirements for Home Health Aide

5 Principles of Changes

- Increase focus and enforcement of patient rights
- Increase quality of care through monitoring of assessment data for performance improvement specific to each agency
- Removes administrative focus of projects that lack adequate evidence of predicting or obtaining improved or preventing harmful patient outcomes.
- Use an improved patient centered, interdisciplinary coordination of care to help meet the needs of the patient.
- Build a continuous, integrated care process utilizing all disciplines for a patient assessment, care plan and delivery to provide improved quality and performance.

Deep Dive into new Conditions of Participation
CoP Details

Definitions

- 484.2 - Definitions
  - New
    - In Advance - before hands-on care
    - Quality Indicator - specific, valid and reliable measure of process
    - Representative - patient designated individual making health decisions
    - Verbal Orders - spoken order
  - Revised
    - Branch Office -
      - Parent agency provides supervision and administrative control of any branch
    - Located sufficiently close removed
  - Eliminated
    - Branch, subunit, supervisors, and home health agency

Patient Care

- 484.50 - Patient Rights
- 484.55 - Patient Comprehensive Assessment
- 484.60 - Care Planning, Service Coordination, Quality of Care
- 484.65 - Quality Assessment and Performance Improvement (QAPI)
- 484.70 - Infection Prevention and Control
- 484.75 - Skilled Professional Services
- 484.80 - Home Health Aide Services
Patient Rights

484.50 - Patient Rights

- The patient and representative (if any), have the right to be informed of the rights in a language and manner the individual understands. The agency must protect and promote the exercising of these rights.

- Significant area that will require additional work:

  - Standards
    - Notice of rights
    - Exercise rights
    - Right of the patient
    - Transfer and discharge
    - Investigation of complaints
    - Accessibility

484.50 Patient Rights - (a) Notice of Rights

- Written AND verbal notice in a language understandable to the patient and accessible (preferred language understandable) for patients with disabilities.
- Verbal notice no later than completion of second skilled visit.
- CMS provides summary of rights “in conversational language and tone” instead of required “word for word”.
- Provided contact information for the HHA Administrator.
- OASIS privacy notices - present for a long time, but now is part of patient rights.
- Patient/representative signature.
- Within 4 business days of initial evaluation visit.
- Distinguish legally authorized representative from patient-selected representative.
- CHARGE requires both written AND verbal notice under timetable, prescribed process when there is an authorized patient representative and guidance on how to communicate the information.

- CURRENT PATIENT RIGHTS NOTICES WILL NEED TO BE REVISED TO COMPLY.
484.50 - Patient Rights - (b) Exercise of Rights

- Exercise of rights
  - Must honor court decisions on competency and recognizing role of appointed representative
  - Patient may select different than court appointed
  - Agency needs to recognize the court appointed over the patient selected one in their case

484.50 - Patient Rights - (c) Rights of the Patient to

- Person and property treated with respect
  - Free from verbal, mental, sexual and physical abuse - including injuries of unknown source, neglect and misappropriation of property
  - May make complaint regarding care
  - Participate in, be informed about and consent OR refuse care in advance of AND during treatment where appropriate with respect to:
    - Completion of the comprehensive assessment
    - Establishing and reviving plan of care
    - Disciplines that will furnish care
    - Visit Frequency
    - Expected outcomes of care, including patient identified goal, and anticipated risk and benefits
    - Any factors that could impact treatment effectiveness
      - New rule is more prescriptive in terms of the detail of information that must be provided *
      - Advanced directive information right is dropped from CoP but 489.100 requirement remains *
    - * = Survey Interpretation Guidance is expected to outline more details on these

484.50 - Patient Rights - (c) Rights of the Patient to - Continued

- Receive all services outlined in the POC
- Have a confidential clinical record and access to record under HIPAA
- Be advised of:
  - Extent which payment for the HH services are expected from Medicaid, Medicare and other federal programs
  - Charges for services that may not be covered by Medicare, Medicaid
  - Charges the Individual may have to pay before care is initiated, and any changes in the information
  - Changes in advance of the next home health visit
- Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 - 405.1204. (HHCN and NOMNC)
484.50 - Patient Rights -
(c) Rights of the Patient to - Continued

- Hotline
- Advised of names, addresses, and telephone numbers of:
  - Agency on Aging
  - Center for Independent Living
  - Protection and Advocacy Agency
  - Aging and disability Resource Center
  - QIO
- Free from any discrimination or reprisal for exercising his/her rights in voiding grievances to the HHA or an outside entity
- Informed of the right to access auxiliary aids and language services and how to access these services

484.50 - Patient Rights -
(d) Transfer & Discharge

- Patient and representative (if any) have a right to be informed of the HHA policies for admission, transfer and discharge. The HHA may only transfer or discharge the patient if
  - Acuity requires another level of care - HHA must arrange for safe and appropriate transfer
  - No payment
  - Physician and HHA agree that goals are met
  - Patient refuses care or elects transfer/discharge
  - Cause - Disruptive, abusive, uncooperative behavior
    - aforepatient, physician at the plan to discharge/transfer
    - Efforts to resolve problems prior to transfer/discharge
    - Provide patient with contact information for the agency/providers
    - Document efforts made to resolve issues
  - Death
  - HHA ceases to operate

484.50 - Patient Rights -
(d) Transfer & Discharge - Continued

- CMS requires physical or electronic documents outlining acceptable reasons for discharge or transfer.
- CMS indirectly included discharge for staff safety reasons, but for cause standards may apply.
- Similarly, CMS did not include “inadequate clinical resources” as a cause basis for discharge.
- HHA need to review state licensing law requirements on discharge and apply standard that most protects patients. Additionally a review of agency policies should be conducted to see which is more restrictive.
484.50 - Patient Rights -
(e) Investigation of Complaints

- Treatment of care
- Mistreatment, neglect, or verbal, mental, sexual, and physical abuse -
  - including injuries of unknown sources, and/or
- Misappropriation of patient property by anyone furnishing services on behalf of the HHA.
- HHA is responsible for asking the necessary questions to determine case of injuries.

- Document both the existence of the complaint and its resolution
- Take action to prevent further potential violations, including retaliation while the complaint is being investigated.
- Staff must immediately report to HHA and other appropriate authorities when they identify, notice, or recognize incidence or circumstances of mistreatment, neglect, or verbal, mental, sexual, and/or physical abuse, including injuries of unknown sources, and/or misappropriations of patient property by anyone furnishing services on behalf of the HHA.
- Reporting consistent with state law
- The new rule adds some more detail to the complaint processing process

484.50 - Patient Rights -
(f) Accessibility

- Information must be provided to patients in plan language and in a manner that is accessible and timely.
- Patients with disabilities -
  - Web site
  - Auxiliary aids at no cost in compliance with ADA
- Limited English Proficiency
  - Language services at no cost including oral and written interpretations
- Ne as a CoP, but essentially already required under LEP rules.
- Provides some flexibility when an “undue burden” under Section 504 of the Rehabilitation Act.
Each patient must receive a patient-specific, comprehensive assessment. For Medicare Beneficiaries, the HHA must verify the patient’s eligibility for the Medicare home health benefit including homebound status, both at the time of initial assessment visit and at the time of the comprehensive assessment.

Standards:
- Initial assessment of patient
- Completion of the comprehensive assessment
- Contents of the comprehensive assessment
- Update of the comprehensive assessment

(a) Initial Assessment Visit

(1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient’s return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled Professional.
484.55 - Comprehensive Assessment

(b) Completion of the Assessment

- (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient’s immediate needs, but no later than 5 calendar days after the start of care.
- (2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.
- (3) When physical therapy, speech language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

Retains all current requirements (e.g. initial assessment 48 hours, 5 day window)

RN must complete except in therapy only cases

484.55 - Comprehensive Assessment

(c) Contents of Assessment

Incorporates elements in the current CoP introductory paragraph. Combines 484.55 - (c) Drug regimen review; (e) incorporation of OASIS data set, add several new items

- (1) The patient’s current health, psychosocial, functional, and cognitive status;
  - Pg 4531 "Assessing a patient’s psychosocial status refers to an evaluation of his or her health, social status, and functional capacity within the community by looking at issues surrounding both a patient’s psychological and social condition (for example, education and marital history)….. We are not requiring the use of any particular tool, nor are we prescribing the extent of the cognitive status assessment. Our goal is to make cognitive assessment a routine practice in HHAs so that HHAs can use this information in developing and implementing the patient-specific plan of care, and so that HHAs identify potentially unmet patient needs that warrant follow-up care with another health care provider, with the HHA making appropriate referrals as needed. We agree that there is crossover between these assessment elements and those items already included in the OASIS. However, those items included in the OASIS may not be sufficient for all patients. That is to say, some patients may require additional assessment beyond what is required in the OASIS"

- (2) The patient’s strengths, goals, and care preferences, including information that may be used to demonstrate the patient’s progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;
  - Pg 4531 “Traditionally the home health plan of care has been developed with a focus on patient deficits that require treatment … This model of care places patients in a passive recipient role that does not optimize the achievement of positive patient outcomes. First, this model does not take into account those patient strengths that can be harnessed by the HHA staff and plan of care to facilitate patient well-being. ….. Each patient has their own set of care preferences, and we would require HHAs to both identify and respect these care preferences to the greatest degree possible. Our goal is to ensure that HHA plan for and provide care that is both patient-directed and in accordance with the physician ordered plan of care"
484.55 - Comprehensive Assessment
(c) Contents of Assessment - continued

- (3) The patient’s continuing need for home care;
- (4) The patient’s medical, nursing, rehabilitative, social, and discharge planning needs;
- (5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

- (6) The patient’s primary caregiver(s), if any, and other available supports:
  - (i) Willingness and ability to provide care
  - (ii) Availability and schedule

- (7) The patient’s representative (if any);
- (8) Incorporation of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary. The OASIS data items determined by the Secretary must include: Clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

484.55 - Comprehensive Assessment
(d) Update of Assessment

- The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient’s condition warrants due to a major decline or improvement in the patient’s health status, but not less frequently than:
  - (1) The last 5 days of every 60 days beginning with the start of care date, unless there is—
    - (i) Beneficiary elected transfer;
    - (ii) Significant change in condition; or
    - (iii) Discharge and return to the same HHA during the 60-day episode.
  - (2) 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;
  - (3) At discharge.
Care Planning

484.60 - Care Planning - Coordination of Services and Quality of Care

- Combines 484.18 Acceptance of patients, plan of care, medical supervision and 484.14(g) Coordination of care
- Care planning, coordination of services, and quality of care
- Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient’s medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient’s needs. The patient’s needs must be identified by a comprehensive assessment. The care plan may also identify the responsible discipline(s), and measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The plan of care must also specify the patient and caregiver education and training that the HHA will provide, specific to the patient’s care needs. Services must be furnished in accordance with accepted standards of practice.

484.60 - Care Planning - Standard

(a) Plan of Care

- Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan.
484.60 - Care Planning - Standard
(a) Plan of Care - continued

1. Plan of care
   - The individualized plan of care must include the following:
     a. All pertinent diagnoses;
     b. The patient’s mental, psychosocial, and cognitive status;
     c. The types of services, supplies, and equipment required;
     d. The frequency and duration of visits to be made;
     e. Prognosis;
     f. Rehabilitation potential;
     g. Functional limitations;
     h. Activities prescribed;
     i. All medications and treatments;
     j. Safety measures to protect against injury;
     k. A description of the patient’s risk for emergency department visits and hospital re-admission and all necessary interventions to address the underlying risk factors;
     l. Patient and caregiver education and training to facilitate timely discharge;
     m. Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;
     n. Information related to any advanced directives; and
   - Any additional forms the HHA or physician may choose to include.

2. All patient care orders, including verbal orders must be recorded in the plan of care
   - The plan of care is an evolving document that outlines the patient’s journey throughout HHA care and treatment. It is essential that the plan of care be reflective of past orders and current orders that are actively ongoing. As new orders are given to initiate or discontinue an intervention, the plan of care is updated to reflect those changes. New versions of the plan of care are created as needed to reflect any change in the plan of care. The plan of care ensures that the patient is in fact receiving the care that is documented in the plan of care as opposed to care being given to the patient in any manner that does not follow the intent of the plan of care.

Advanced Directives moved to Medicare Provider Agreement in 489.100

484.60 - Care Planning - Standard
(b) Conformance with Physician orders

1. Drugs, services, and treatments are administered only as ordered by the physician who is responsible for the home health plan of care.
2. Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, and after an assessment of the patient to determine for contraindications.
3. Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA’s internal policies.
4. When services are provided on the basis of a physician’s verbal orders, a registered nurse, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA’s policies must document the orders in the patient’s clinical record, and steps, date, and time the orders. Verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA’s internal policies.
484.60 - Care Planning -
(c) Review and Revision of Plan of Care

1. The individualized plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA must promptly alert the physician who is responsible for the HHA plan of care to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

2. A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care. Verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

3. Revisions to the plan of care must be communicated as follows:
   (i) Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and the physician who is responsible for the HHA plan of care.
   (ii) Any revisions related to plans for the patient's discharge must be communicated to the 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 for providing care and services to the patient after discharge from the HHA (if any).

The commenter requested that CMS clarify whether all changes to the plan of care require the plan of care to be re-signed by the physician, and if not, explicitly when that would and would not be required.

Response: The signature of the physician who is responsible for issuing orders related to the condition(s) that led to the initiation of home health services should be on all iterations of the individualized plan of care for each patient in accordance with the requirements of §484.60(a).

484.60 - Care Planning -
(d) Coordination of Care

1. The HHA must:
   (1) Assure communication with all physicians involved in the plan of care.
      - b. CMS: "The purpose of assuring communication and integrating orders is to avoid duplication or contradictory orders, and/or to extend care planning or collaborative planning to areas not directly served by the patient's primary care physician. We would prefer that in a non-emergency situation the plan of care be reviewed and signed by the primary care physician and, if not, that the plan of care be documented as communicating with the primary care physician and that the orders be authenticated and dated by the primary care physician and any other involved physicians.
   (2) Integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.
   (3) Coordinate care delivery, to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

The HHA must provide training, as necessary, to ensure a timely discharge.
484.60 - Care Planning
(e) Written information to the patient

- The HHA must provide the patient and caregiver with a copy of written instructions outlining:
  - (1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.
  - (2) Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.
  - (3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.
  - (4) Any other pertinent instruction related to the patient’s care and treatments that the HHA will provide, specific to the patient’s care needs.
  - (5) Name and contact information of the HHA clinical manager.

- Replaces requirement under patient rights in proposed rule

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Quality Assessment and Performance Improvement (QAPI)

484.65 Quality Assessment and Performance Improvement (QAPI) - Standards

- The HHA must develop, implement, evaluate, and maintain an effective, ongoing, data-driven QAPI program. The HHA’s governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including hospital admission and readmission rates; identifies patterns of care and practices that result in care that is effective across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

- Standards:
  - Standard 1: Program scope
  - Standard 2: Program data
  - Standard 3: Program activities
  - Standard 4: Performance improvement projects
484.65 Quality Assessment and Performance Improvement (QAPI)

Program Scope

1. The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in these indicators will improve health outcomes, patient safety, and quality of care.
2. The HHA must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, HHA services, and operations.

Program Data

1. The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.
2. The HHA must use the data collected to:
   a. Monitor the effectiveness and safety of services and quality of care; and
   b. Identify opportunities for improvement.
3. The frequency and detail of the data collection must be approved by the HHA’s governing body.

(c) Program Activities

1. The HHA’s performance improvement activities must:
   a. Focus on high risk, high volume, or problem-prone areas;
   b. Consider incidence, prevalence, and severity of problems in those areas; and
   c. Lead to an immediate correction of any identified problem that directly or potentially threatens the health and safety of patients.
2. Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.
3. The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.
484.65 Quality Assessment and Performance Improvement (QAPI)
(d) Performance improvement projects

- Beginning **January 13, 2018** HHAs must conduct performance improvement projects.
  
  1. The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA’s services and operations.
  
  2. The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.

This is the ONLY standard (d) that is delayed in QAPI. All others are effective 7/13/17.

484.65 Quality Assessment and Performance Improvement (QAPI)
(e) Executive Responsibilities

- The HHA’s governing body is responsible for ensuring the following:
  
  1. That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;
  
  2. That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness;
  
  3. That clear expectations for patient safety are established, implemented, and maintained; and
  
  4. That any findings of fraud or waste are appropriately addressed.
484.70 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.
> (a) Prevention. The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases. (b) Control. The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include: (1) A method for identifying infectious and communicable disease problems; and (2) A plan for the appropriate actions that are expected to result in improvement and disease prevention. (c) Education. The HHA must provide infection control education to staff, patients, and caregivers.

Already covered if you're Accredited. New if not accredited.

Skilled Professional Services

484.75 Skilled Professional Services - Standards

Combines and revises 484.30 Skilled nursing services; 484.32 Therapy services and 484.34 Medical social services.

> Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in § 409.44 of this chapter, and physician and medical social work services as specified in § 409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

Standards:

> (a) Provision of services by skilled professionals
> (b) Responsibilities of skilled professionals
> (c) Supervision of skilled professional assistants
484.75 Skilled Professional Services - (a) Provision of services by skilled professionals

Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under §484.115 and who practice according to the HHA’s policies and procedures. Comply with personnel qualification at 484.115.

484.75 Skilled Professional Services - (b) Responsibilities of skilled professionals

Skilled professionals must assume responsibility for, but not be restricted to the following:

- (1) Ongoing interdisciplinary assessment of the patient;
- (2) Development and evaluation of the plan of care in partnership with the patient, representative, and caregiver(s);
- (3) Providing services that are ordered by the physician as indicated in the plan of care;
- (4) Patient, caregiver, and family counseling;
- (5) Patient and caregiver education;
- (6) Preparing clinical notes;
- (7) Communication with the physician who is responsible for the home health plan of care and other health care practitioners (as appropriate) related to the current plan of care;
- (8) Participation in the HHA’s QAPI program; and
- (9) Participation in HHA-sponsored in-service training.

Rather than specific tasks for each discipline, broad expectations for all skilled professionals:

484.75 Skilled Professional Services - (c) Supervision of Skilled Professional Assistants

- (1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).
- (2) 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.
- (3) Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m).
484.80 Home Health Aide Services - Standards

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

1. Home health qualifications
2. Content and duration of home health aide classroom and practical training
3. Competency evaluation
4. In-service training
5. Qualifications for instructors conducting classroom and supervised practical training
6. Eligible training and competency evaluation organizations
7. Home health aide assignments and duties
8. Supervision of home health aides
9. Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit

484.80 Home Health Aide Services - (a) Home Health Aide Qualifications

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

1. A qualified home health aide is a person who has successfully completed:
   1. A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or
   2. A competency evaluation program that meets the requirements of paragraph (c) of this section; or
   3. A 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
   4. The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.

2. A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual’s most recent completion of the program, none of the services furnished by the individual as described in §409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.
484.80 Home Health Aide Services -
(b) Content and duration of home health aide classroom and supervised practical training

1. Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

2. A minimum of 14 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

3. A home health aide training program must address each of the following subject areas:
   (1) 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.
   (2) Observation, recording, and documentation of patient status and the care or service furnished.
   (3) Basic infection prevention and control procedures.
   (4) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
   (5) Maintenance of a clean, safe, and healthy environment.
   (6) Recognizing emergencies and the knowledge of instituting emergency procedures and their application.
   (7) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—
      (A) Bed bath;
      (B) Sponge, tub, and shower bath;
      (C) Hair shampooing in sink, tub, and bed;
      (D) Nail and skin care;
      (E) Oral hygiene;
      (F) Toileting and elimination;
   (8) Normal range of motion and positioning;
   (9) Adequate nutrition and fluid intake;
   (10) Recognizing and reporting changes in skin condition;
   (11) Any other task that the HHA may choose to have an aide perform as permitted under state law.
   (12) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(c) Competency Evaluation

An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

1. The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

2. A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

3. The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

4. A home health aide is not considered competent in any task for which he or she is evaluated as "unsatisfactory." An aide must not perform tasks without the direct supervision of a registered nurse until he or she has successfully completed a subsequent evaluation in which he or she has demonstrated competence in that task. An aide is considered to have successfully completed a subsequent evaluation if the aide has an "unsatisfactory" rating in more than one area of the evaluation.

5. The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.
484.80 Home Health Aide Services -
(d) In-Service Training

A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

1. In-service training may be offered by any organization and must be supervised by a registered nurse.
2. The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

484.80 Home Health Aide Services -
(e) Qualifications for instructors conducting classroom and supervised practical training

Classroom and supervised practical training must be performed by a registered nurse who possesses a 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.

484.80 Home Health Aide Services -
(f) Eligibility Training and Competency Evaluation Organizations

A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

1. Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or
2. Permitted an individual who does not meet the definition of a “qualified home health aide” as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or
3. Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the state); or
4. Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; or
484.80 Home Health Aide Services -
(f) Eligibility Training and Competency Evaluation Organizations - Continued

- (5) Was found to have compliance deficiencies that endangered the health and safety of the HHAs patients, and had temporary management appointed to oversee the management of the HHA; or
- (6) Had all or part of its Medicare payments suspended; or
- (7) Was found under any federal or state law to have:
  - (i) Had its participation in the Medicare program terminated; or
  - (ii) Been assessed a penalty of $5,000 or more for deficiencies in federal or state standards for HHAs; or
  - (iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or
  - (iv) Operated under temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHAs patients; or
  - (v) Been closed, or had its patients transferred by the state; or
  - (vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

484.80 Home Health Aide Services -
(g) Home health aide assignments and duties - Continued

- (1) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

- (2) A home health aide provides services that are:
  - (i) Ordered by the physician;
  - (ii) Included in the plan of care;
  - (iii) Permitted to be performed under state law; and
  - (iv) Consistent with the home health aide training.

- (3) The duties of a home health aide include:
  - (i) The provision of hands-on personal care;
  - (ii) The performance of simple procedures as an extension of therapy or nursing services; and
  - (iii) Assistance in ambulation or exercises; and
  - (iv) Assistance in administering medications ordinarily self administered.

- (4) Home health aides:
  - must be members of the interdisciplinary team;
  - must report changes in the patient's condition to a registered nurse or other appropriate skilled professional;
  - must complete appropriate records in compliance with the HHAs policies and procedures.
484.80 Home Health Aide Services - (h) Supervision of aides

1) (a) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services, a registered nurse or other appropriate skilled professional who is familiar with the patient, the patient’s plan of care, and the written patient care instructions described in §484.80(g), must make an onsite visit to the patient’s home no less frequently than every 14 days. The home health aide does not have to be present during this visit.

2) (i) If an area of concern in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

3) (ii) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:
   (a) Following the patient’s plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;
   (b) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;
   (c) Demonstrating competency with assigned tasks;
   (d) Complying with infection prevention and control policies and procedures;
   (e) Reporting changes in the patient’s condition; and
   (f) Honoring patient rights.
484.80 Home Health Aide Services - (h) Supervision of aides - Continued

(i) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA’s responsibilities also include, but are not limited to:

- Ensuring the overall quality of care provided by an aide;
- Supervising aide services as described in paragraphs (h)(1) and (2) of this section; and
- Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

484.80 Home Health Aide Services - (i) Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit

An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.
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

Emergency Preparedness takes effect in November 2017, NOT in July with CoP

484.100 Compliance with Federal, State, and local laws and regulations related to the health and safety of patients

Incorporates 484.14(j) laboratory services

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing requirements, the HHA must be licensed in accordance with those requirements.

- (a) Disclosure of ownership and management information and management information.
- The HHA must comply with the requirements of part 480 subpart C of this chapter. The HHA also must disclose to the state survey agency at the time of the HHA's initial request for certification and for each subsequent survey:
  - (1) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in §420.201, §420.202, and §420.206 of this chapter.
  - (2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in §420.201, §420.202, and §420.206 of this chapter.
  - (3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.
- (b) Licensing. The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

484.100 Compliance with Federal, State, and local laws

(c) Laboratory Services

- (1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. **The HHA may not substitute HHA equipment for a patient's equipment when assisting with self-administered tests.**
- (2) If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

**Page 484.100 may not substitute HHA-owned self-administered testing equipment for patient-owned self-administered testing equipment. As stated in the preamble to the proposed rule, “agencies may use their own self-administered testing equipment for a short, defined period of time when the patient has not yet obtained his or her own testing equipment, such as in the days immediately following physician orders to obtain the testing equipment, when a patient may not have the time and resources immediately available to obtain their own equipment.”**
484.105 Organization and administrative services

(a) Governing Body

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient’s plan of care, for each patient’s medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

(b) Administrator

(1) Be appointed by and report to the governing body;

(2) Be responsible for all day-to-day operations of the HHA;

(3) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;

(4) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.

(5) 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.

(6) The administrator or a pre-designated person is available during all operating hours.
484.105 Organization and administrative services
(c) Clinical Manager
- Clinical manager. One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following:
  1. Making patient and personnel assignments,
  2. Coordinating patient care,
  3. Coordinating referrals,
  4. Assuring that patient needs are continually assessed, and
  5. Assuring the development, implementation, and updates of the individualized plan of care.

- Can have multiple clinical managers
- Replaces standard for supervising nurse
- Pg 4550 - Clinical Manager

484.105 Organization and administrative services
(d) Parent Branch Relationship
- (1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA’s request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.
- (2) The parent HHA provides direct support and administrative control of its branches.
- (e) Services under arrangement - no change
- (f) Services furnished - retains one service directly
- (g) Outpatient therapy - no change
- (h) Institutional planning – annual budget; capital expenditure; preparation of plan and budget; annual of plan and budget

Subunits
- Subunit designation to be eliminated and must be converted to a parent or a branch by 7/13/17

- Pg 4551: "Subunits are already the equivalent of stand-alone HHAs and will be able to continue functioning as such, retaining the need to change to branches. Since there would be no threat to an HHA’s ability to function and serve its patients, we do not agree that it would be appropriate for CMS to allocate survey resources to those HHAs that desire to, but do not need to, convert a subunit to a branch. Thus, the current process and priority levels will remain the same."

- Agencies in states with a moratorium may have problems as branches are not being approved. If not a branch or a parent by 7/13/17, then any claims out of the subunit will be denied. Action needs to start now if converting to a branch as time is required. 855 work is needed to get a new provider number if trying to change to a parent.
Clinical Record

484.110 Clinical Record

(a) Contents of Clinical Record

- The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician who is responsible for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

- Standards
  - (a) Contents of the clinical record
  - (b) Authentication
  - (c) Retention of records
  - (d) Protection of records
  - (e) Retrieval of records

- (a) Contents of Clinical Record

  - (1) 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;
  - (2) All interventions, including medication administration, treatments, and services, and responses to these interventions;
  - (3) Goals in the patient's plans of care and the patient's progress toward achieving them;
  - (4) Contact information for the patient and the patient's representative (if any);
  - (5) Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA;
  - (6) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA within 5 business days of the patient's discharge;

- (b) (i) 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;
- (ii) 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.

*Contents not specified. Deferred to another Rule related to the IMPACT act*
484.110 Clinical Record
(b) 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.

- Pp 4550… To clarify, “timed” means the actual time that an event occurred, which is not necessarily the time when the documentation was inserted into the record. The date and time requirement applies to all entries in the record. We believe it is extremely important that the clinical record accurately reflects a clear account of the patient’s entire course of care. The clinical record should tell a linear story of the course of the patient’s care that is managed and delivered by the HHA. Without timing entries, there is the risk for a disjointed record and a possibility for the occurrence of avoidable medical errors.

- Interpretive guidelines will need to be consulted to see if every procedure needs to be dated and timed or whether date and time on a visit note are sufficient.

484.110 Clinical Record
(c) Retention of Records

- (1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.

- (2) The 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
(d) Protection of records

- The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding protected health information set out at 45 CFR parts 160 and 164.

- (e) 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).
Personal Qualifications

484.115 Personal Qualifications

- HHA staff are required to meet the following standards:
  - Standards (a)-(m)
  - (a) Administrator, home health agency.
  - (1) 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.
  - (2) 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;
    - has experience in health service administration, with at least 1 year of supervisory or administrative experience, and
    - has experience in health service administration, with at least 1 year of supervisory or administrative experience.
  - (b) Clinical manager. A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

484.115 Personal Qualifications

- (m) Social worker. A person who has a master’s or doctoral degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.
- (n) Speech-language pathologist. A person who has a master’s or doctoral degree in speech language pathology, and who meets either of the following requirements:
  - (1) is licensed as a speech language pathologist by the state in which the individual furnishes such services; or
  - (2) in the case of an individual who furnishes services in a state which does not license speech-language pathologists:
    - (i) has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience).
Thanks for Attending!

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Coming your way through email:
  - Webinar recording
  - Handouts
  - More resources
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