Subpart C – Organizational Environment

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

Move to Patient Centered Care

- The IOM (Institute of Medicine) defines **patient-centered care** as: "Providing **care** that is respectful of, and responsive to, individual **patient** preferences, needs and values, and ensuring that **patient** values guide all clinical decisions." May 15, 2015

Licensing

- The agency, 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

Laboratory Services

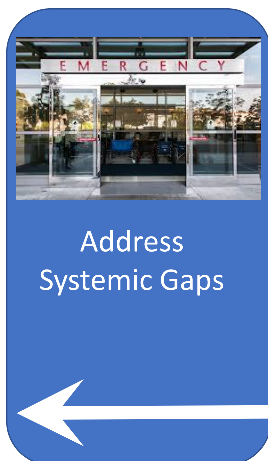
- If the agency engages in lab testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, the testing must be in compliance with all applicable requirements. The agency may not substitute its equipment for a patient’s equipment when assisting with self-administered tests.
- If the agency refers specimens for lab testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services.

484.102- Emergency Preparedness

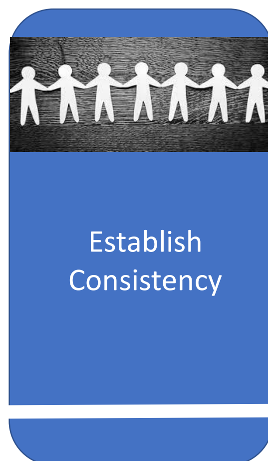
Emergency Preparedness

- The Home Health Agency (HHA) must comply with all applicable Federal, State and local emergency preparedness requirements. The Agency must establish and maintain and emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to the following elements:
  - Emergency Plan
  - Policies and procedures
  - Communication Plan
  - Training and testing

Goals

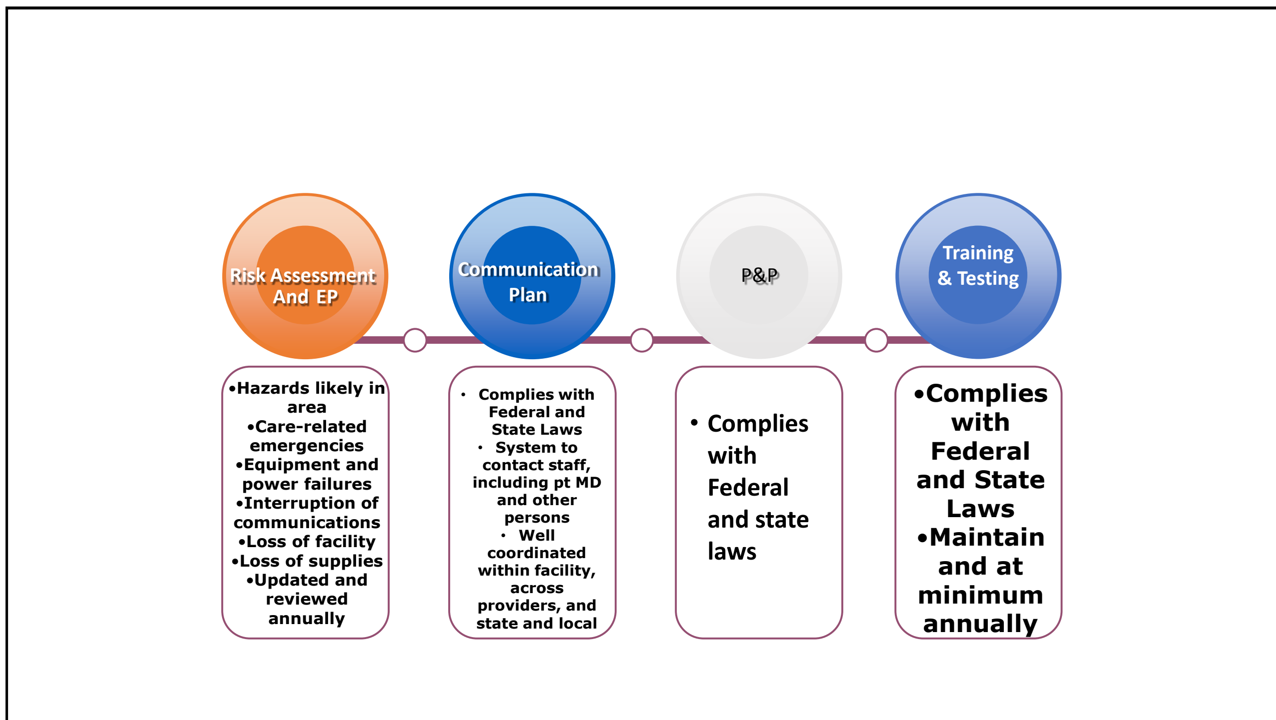


Address Systemic Gaps



Establish Consistency

Encourage Coordination



Risk Assessment and Emergency Preparedness

- HVA (Hazards Vulnerability Analysis)

1. Can you identify and prioritize likely hazards?
2. Based on this, what are vulnerabilities?
3. What is the capacity and capability?
4. What risks should be presented to the organization and other providers?

<u>Update at least annually</u>

Risk Ranking Matrix

Severity \ Likelihood	1	2	3	4	5
5	High Risk	High Risk	Extremely High Risk	Extremely High Risk	Extremely High Risk
4	High Risk	High Risk	High Risk	Extremely High Risk	Extremely High Risk
3	Low Risk	Low Risk	Medium Risk	Medium Risk	Extremely High Risk
2	Low Risk	Low Risk	Medium Risk	Medium Risk	Medium Risk
1	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk

Tools already developed

- Pennsylvania Public Health RA tool
- Health Hazard Assessment and Prioritization
- UCLA Hazard Risk Assessment Instrument
- Kaiser Permanente Hazard Vulnerability Analysis Tool
- Community Hazard Vulnerability Assessment
- Comprehensive Preparedness Guide 201:Threat and Hazard ID and Risk Assessment Guide

Health Hazard Assessment

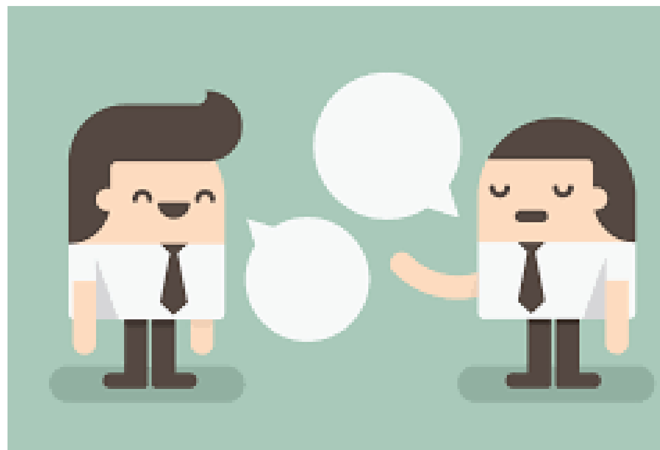
- Excel format
- Identifies, ranks, and prioritizes the health and medical impacts of potential hazards relevant to a specific jurisdiction/agency based on user-provided input (scores)
- Provides 6 step hazard vulnerability assessment process

Hazard mitigation (reduction)

- Determining your community's probable disaster threats
- Identifying potential hazards in your workplace
- Taking preventive action to reduce the hazards

Communication Plan

1. Develop a communication plan that complies with both Federal and State laws.
2. Coordinate patient care within the facility, across health care providers, and with state and local public health departments and emergency management systems.
3. Review and update annually



Communication

- Must contain
- (1) Names and contact information
  (i) Staff.
  (ii) Entities providing services under arrangement.
  (iii) Patients' physicians.
  (iv) Volunteers.
- (2) Contact information for the following:
  - (i) Federal, State, tribal, regional, or local emergency preparedness staff.
  - (ii) Other sources of assistance

Communication

- (3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies
- (4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to maintain the continuity of care.
- (5) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

Communication

- (6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee

Staff Education

- Include emergency preparedness in staff orientation programs, establishing it as part of their job responsibilities with the assurance they will not be asked to put themselves at risk as part of agency response;
- Hold regular briefings on seasonal threats, such as flooding, heat waves, or snowstorms;
- During staff education, incorporate basic lessons in ethics in emergency situations;
- Establish points of communication for staff via radio station, website, text message, etc., well in advance. Test their responses no less than once or twice a year.

External operations

- Plan to ensure all outside agencies are notified. This requires the maintenance and distribution of an up-to-date list of all key agencies (EMS, local emergency management, local public health, Regional Healthcare Coalitions or other health care systems, etc). This communication plan should include contact information and protocols for:
  - Local office of emergency management
  - Local public health
  - Regional Healthcare Coalition
  - Community partner information and plans

Why Needed?

- Emergency planners often lack awareness of the vulnerability and complex care requirements of many elders
- Communities (& stakeholders) have varied levels of preparedness, planning and response capabilities/capacities for elders during disasters
- Community planning may not be sufficient to identify, engage and integrate all key stakeholders involved in elder care during disasters

Communication Best Practices

- Determine what means of alternate communication is available during a power outage (e.g. hard-wired landlines, fax lines, website accessible from mobile phones, ham radio, etc.) and script out, if possible, the messages to be communicated;
- Keep a list of hard-wired and fax lines as well as cell phone numbers; and
- Be language savvy – identify language needs and literacy levels in advance, scripting out messages to make sure all pertinent information is included.

Policy and Procedure

1. Develop and implement policies and procedures based on the emergency plan and risk assessment.
2. Policies and procedures must address a range of issues including subsistence needs, evacuation plans, procedures for sheltering in place, tracking patients and staff during an emergency.
3. Review and update policies and procedures at least annually.

Policy and Procedure

1. There must be a policy defining the agency's 24-hour, 7-day-a-week coverage, or coverage consistent with the agency's hours of operation. It must be reviewed no less than once a year.
2. Annual Policy Update and Staff Training: The plan must include an annual review and update of the emergency plan and a policy that addresses staff orientation to the plan and defines staff roles during an emergency. It is also recommended that plans include evidence of staff education targeted at employees' specific roles (paraprofessional, clinical, administrative, etc.)

Policy and Procedure

- A Community Partner Contact List of local health department, local emergency management, emergency medical services and law enforcement and other partnering health organizations as well as a policy that addresses how this information will be kept current.
- Policies should be maintained that address participation in agency-specific drills or community- wide drills and exercises. This can also include participation with exercises conducted by emergency management, public health and/or regional healthcare coordinators. As a best- practice, it is also recommended that agencies include in their plans evidence which shows planning for and participation in drills and exercises, plus evaluation and plan updates resulting from after-action reports.

Testing and Training

1. Develop and maintain training and testing programs, including initial training in policies and procedures.
2. Demonstrate knowledge of emergency procedures and provide training at least annually.
3. Conduct drills and exercises to test the emergency plan.

Training Program to Include

- Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
- Provide emergency preparedness training at least annually.
- Maintain documentation of the training.
- Demonstrate staff knowledge of emergency procedures.

Testing to Include

- The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following
- Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

Testing to Include

- Conduct an additional exercise that may include, but is not limited to the following:
- (A) A second full-scale exercise that is community-based or individual, facility based.
- (B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
- Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

Home Health Specifics

- Home health agencies and hospices required to inform officials of patients in need of evacuation.
- Alternative contact information on patients continuously updated
- Updated risk roster-Who maintains, how is it communicated? Do you have a patient identification of risk that is being followed?
- Identification of a 24/7 emergency contact telephone number and e-mail address of the emergency contact person and alternate
- A call down list of agency staff and a procedure which addresses how the information will be kept current

Home Health Specifics

- A contact list of community partners, including the local emergency management, local health department, regional healthcare coalition, emergency medical services, law enforcement, utilities, durable medical equipment (DME) provider, and medical gas vendors. Including, a policy that addresses how this information will be kept current
- Collaboration with the local emergency manager, local health department, regional healthcare coalition and other community partners in planning efforts, including a clear understanding of the agency's role and responsibilities in the county's comprehensive emergency management plan

484.105-Organization and Administration of Services

Previously 484.14

Organization and Administration of services

- The agency 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 agency 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 agency must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

Governing Body

- Must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and operational plans; and its quality improvement program

Administrator

- Must be appointed by and report to the governing body
- Be responsible for the day to day operations of the agency
- Ensure that a clinical manager is available during all operating hours
- Ensure that the agency employs qualified personnel, including assuring the development of personnel qualifications and policies.
- When 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. May be the clinical manager
- Administrator or pre-designated person must be available during all operating hours.

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
  5. Assuring the development, implementation and updates of the individualized plans of care

Parent-branch relationship

- The parent is responsible for reporting all branch locations of the agency to the state survey agency at the time of the agency's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.
- Provides direct support and administrative control of branches

Services under arrangement

- The agency must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements.
- Must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the agency's patients. Must maintain overall responsibility for the services provided under arrangement.
- Must not be excluded from participation in Medicare
- Agency responsible for patient care

Services furnished

- Skilled nursing services and at least one other therapeutic service (PT, SLP, OT, MSW, or Aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An agency must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.
- All services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

Outpatient PT or SLP Services

- If you provide outpatient services you must meet all applicable conditions

Institutional planning

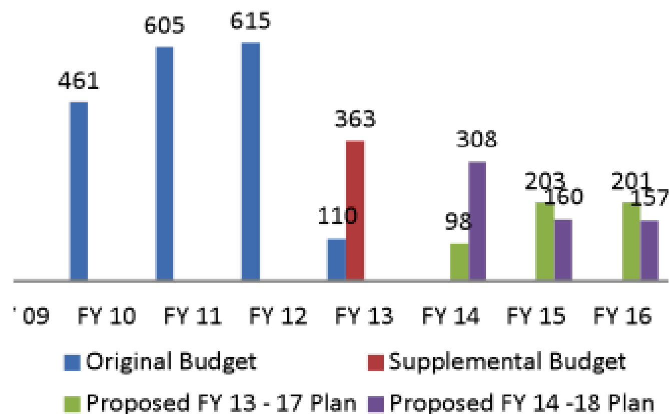
- The agency, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

Annual operating budget

- There is an annual operating budget that includes all anticipated income and expenses related to items that would under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

Capital Expenditure Plan

- 3 year plan including current operating year
- If over $600K-studies, replacement of land, etc are included
- If source of funding is government funded, then documentation if it is required to conform to standards
- Prepared under the direction of the governing body.
- Annual review of plan



484.110- Clinical Records

Previously 484.48

Clinical Records

- The agency must maintain a clinical record containing past and current information for every patient accepted by the agency 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(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

Contents of the Clinical Record

- Current Comprehensive Assessment
- All interventions, including medication administration, treatments and services, and responses to those interventions
- Goals in the patients plans of care and the patient's progress toward achieving them
- Contact information for the patient, the patient's representative (if applicable, and the patient's primary caregiver.
- 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 agency

Contents of the Clinical Record

- A completed discharge summary that is sent to the PCP or other health care professional who will be responsible for providing care and services to the patient after discharge from the agency within 5 business days of the patient's discharge
- A completed transfer summary 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 agency becomes aware of the transfer

Authentication

- All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and title (occupation), or a secured computer entry by a unique identifier, or a primary author who has reviewed and approved the entry.

Protection of records

- The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The agency must be in compliance with the rules regarding PHI.

Retrieval of clinical records

- 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)

484.115- Personnel Qualifications

Previously 484.4

Administrator

- Prior to 7/31/17-must be
  - A licensed physician
  - Registered Nurse, or
  - Has training and experience in health services administration and at least 1 year of supervisory administrative experience in home health care or related health care program
- After 7/31/17-must be
  - Licensed physician, a RN, or holds an undergraduate degree, AND
  - Has experience in health services administration, with at least 1 year of supervisor or administrative in home health care or a related health care program.

Audiologist

- Meets education and experience requirements for a Certificate of Clinical Competence in audiology
- Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification

Clinical Manager

- Must be a:
  - Licensed physician
  - Physical therapist
  - Speech language pathologist
  - Occupational therapist
  - Audiologist
  - Social Worked
  - Registered Nurse

Occupational Therapists, Physical Therapists

- Varying degrees of licensure and educational requirements depending on when the therapist was licensed.

OTA and LPTA

- Licensed in the state applicable
- Graduate of, and successful completion of programs recognized by the license, depending on when the employee became a licensed assistant.

Social Work Assistant

- A person who provides services under the supervision of a qualified Social Worker and
  - Has baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or
  - Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on proficiency examination conducted, approved, or sponsored by the US Public Health Services,

Social Worker

- A person who has a master's degree 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 health care setting.

Speech Language Pathologist

- A person who has a master's degree or doctoral degree in speech-language pathology, and who meets either of the following requirements.
  - Is licensed as a SLP by the state in which the individual furnishes such services, or
  - In the case of an individual who furnishes services in a state hcih does not licenses SLP-has to complete 350 clock hours of supervised clinical practicuum
  - Performed not less than 9 months of supervised full time SLP services after obtaining a master's or doctoral degree in SLP or a related field
  - Successfully completed a national exam in SLP approved by the Secretary.

HR files

- Need to review job descriptions and include the duties and requirements of personnel.

Subpart A – General Provisions

484.1 – Basis and Scope

- Unchanged

484.2 – Definitions

- Sub-unit has been eliminated
- Quality indicator ("specific, reliable, valid measure")
- Subdivision (component of a multi-functional health agency, such as a hospital-based agency)
- Summary report
- Supervised practical training (training in a lab or other setting)
- Verbal order ("spoken" MD order, then transcribed)
- Removed-
  - Nonprofit home health agency
  - Progress note
  - Subunit
  - Supervision
  - (note: Summary note not removed, but no longer required)

484.2 – Definitions

- 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)

484.2 – Definitions

- Clinical Note-Added "timed" (contact with a patient that is written, timed, and dated)
- Added: During a given period of time-
- Timed means-<u>Time that order received or a service provided.</u>
- 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)

484.2 – Definitions

- Added-In advance-HHA staff must complete the task prior to performing any hands on care or any patient educations.
- Representative (legal representative or patient-selected representative)
  - Patient's legal representative, such as guardian, who makes health-care 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.

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

QUESTIONS

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