The following information is provided to individuals for the sole purpose of preparing to complete education courses which will allow that individual to complete the necessary education prerequisites required to become a Home Health Administrator or Alternate Administrator. This information was obtained from the DADS website on June 15, 2012. Because unlike a nursing home or assisted living facility where patients come to you, you are entering a patient’s home therefore you must be held to a higher standard. There is a greater level of trust involved. It remains the full responsibility of each agency to remain in compliance with applicable federal, state, and local regulations and/or laws governing HCSSAs and the services they provide. Agencies must be able to demonstrate compliance with applicable regulations and/or laws during the initial HCSSA survey and during any subsequent visits.
SUBCHAPTER A
§97.1 ~ PURPOSE AND SCOPE
(a) Purpose
(1) The purpose of this chapter is to implement the Health and Safety Code (HSC), Chapter 142, which provides the Department of Aging and Disability Services (DADS) with the authority to adopt minimum standards that a person must meet in order to be licensed as a Home and Community Support Services Agency (HCSSA) and also to qualify to provide certified home health services. The requirements serve as a basis for licensure and survey activities.
(2) Except as provided by the HSC §142.003 relating to Exemptions from Licensing Requirement, a person, including a health care facility licensed under the HSC, may not engage in the business of providing home health, hospice, or Personal Assistance Services (PAS), or represent to the public that the person is a provider of home health, hospice, or PAS for pay without a HCSSA license authorizing the person to perform those services issued by DADS for each place of business from which home health, hospice, or PAS is directed. A certified HCSSA must have a license to provide certified home health services.
(b) Scope. This chapter establishes the minimum standards for acceptable quality of care, and a violation of a minimum standard is a violation of law. These minimum standards are adopted to protect clients of HCSSAs by ensuring that the clients receive quality care, enhancing their quality of life.
(c) Limitations. Requirements established by private or public funding sources such as health maintenance organizations or other private third-party insurance, Medicaid (Title XIX of the Social Security Act (SSA)), Medicare (Title XVIII of the SSA), or state-sponsored funding programs are separate and apart from the requirements in this chapter for agencies. No matter what funding sources or requirements apply to an agency, the agency must still comply with the applicable provisions in the statute and this chapter. The agency is responsible for researching availability of any funding source to cover the services the agency provides.

§97.2 ~ DEFINITIONS
The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.
(1) Accessible and Flexible Services ~ services which are delivered in the least intrusive manner possible and are provided in all settings where individuals live, work, and recreate.
(2) Administration of Medication ~ the direct application of any medication by injection, inhalation, ingestion, or any other means to the body of a client. The preparation of medication is part of the administration of medication and is the act or process of making ready a medication for administration, including the calculation of a client's medication dosage; altering the form of the medication by crushing, dissolving, or any other method; reconstitution of an injectable medication; drawing an injectable medication into a syringe; preparing an intravenous admixture; or any other act required to render the medication ready for administration.
(3) Administrative Support Site ~ a facility or site where an agency performs administrative and other support functions but does not provide direct home health, hospice, or personal assistance services. This site does not require an agency license.
(4) Administrator ~ the person who is responsible for implementing and supervising the administrative polices and operations of a home and community support services agency and for administratively supervising the provision of all services to agency clients on a day-to-day basis.
(5) **Advanced Practice Nurse** ~ a registered nurse who is approved by the Texas Board of Nursing (BON) to practice as an advanced practice nurse and who maintains compliance with the applicable rules of the BON. See the BON’s definition in 22 TAC §221.1.

(6) **Advisory Committee** ~ a committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup, established for the purpose of obtaining advice or recommendations on issues or policies that are within the scope of a person’s responsibility.

(7) **Affiliate** ~ with respect to an applicant or license holder, which is:

(A) a corporation means each officer, director, and stockholder with direct ownership of at least 5%, subsidiary, and parent company;

(B) a limited liability company means each officer, member, and parent company;

(C) an individual means:

(i) the individual's spouse;

(ii) each partnership and each partner thereof of which the individual or any affiliate of the individual is a partner; and

(iii) each corporation in which the individual is an officer, director, or stockholder with a direct ownership or disclosable interest of at least 5%.

(D) a partnership means each partner and any parent company; and

(E) a group of co-owners under any other business arrangement—means each officer, director, or the equivalent under the specific business arrangement and each parent company.

(8) **Agency** ~ a home and community support services agency.

(9) **Alternate Delivery Site** ~ a facility or site, including a residential unit or an inpatient unit:

(A) that is owned or operated by an agency providing hospice services;

(B) that is not the hospice's principal place of business. For the purposes of this definition, the hospice’s principal place of business is the parent office for the hospice;

(C) that is located in the geographical area served by the hospice; and

(D) from which the hospice provides hospice services.

(10) **Applicant** ~ the owner of an agency that is applying for a license under the statute. This is the person in whose name the license will be issued.

(11) **Assistance with Self-administration of Medication** ~ any needed ancillary aid provided to a client in the client's self-administered medication or treatment regimen, such as reminding a client to take a medication at the prescribed time, opening and closing a medication container, pouring a predetermined quantity of liquid to be ingested, returning a medication to the proper storage area, and assisting in reordering medications from a pharmacy. Such ancillary aid includes administration of any medication when the client has the cognitive ability to direct the administration of their medication and would self-administer if not for a functional limitation.

(12) **Association** ~ a partnership, limited liability company, or other business entity that is not a corporation.

(13) **Audiologist** ~ a person who is currently licensed under the Occupations Code, Chapter 401, as an audiologist.

(14) **Bereavement** ~ the process by which a survivor of a deceased person mourns and experiences grief.

(15) **Bereavement Services** ~ support services offered to a family during bereavement. Family includes a significant others.

(16) **Branch Office** ~ a facility or site in the service area of a parent agency from which home health or personal assistance services are delivered or where active client records are maintained. This does not include inactive records that are stored at an unlicensed site.
(17) **Care Plan** ~
(A) a written plan prepared by the appropriate health care professional for a client of the home and community support services agency; or
(B) for home dialysis designation, a written plan developed by the physician, registered nurse, dietitian, and qualified social worker to personalize the care for the client and enable long- and short-term goals to be met.

(18) **Case Conference** ~ a conference among personnel furnishing services to the client to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care or care plan.

(19) **Certified Agency** ~ a HCSSA, or portion of the agency, that:
(A) provides a home health service; and
(B) is certified by an official of the Department of Health and Human Services (HHS) as in compliance with conditions of participation in SSA Title XVIII.

(20) **Certified Home Health Services** ~ home health services that are provided by a certified agency.

(21) **CHAP** ~ Community Health Accreditation Program, Inc. An independent, nonprofit accrediting body that publicly certifies that an organization has voluntarily met certain standards for home and community-based health care.

(22) **Chief Financial Officer** ~ an individual who is responsible for supervising and managing all financial activities for a home and community support services agency.

(23) **Client** ~ an individual receiving home health, hospice, or personal assistance services from a licensed home and community support services agency. This term includes each member of the primary client's family if the member is receiving ongoing services. This term does not include the spouse, significant other, or other family member living with the client who receives a one-time service (e.g., vaccine) if the spouse, significant other, or other family member receives the service in connection with the care of a client.

(24) **Clinical Note** ~ a dated and signed written notation by agency personnel of a contact with a client containing a description of signs and symptoms; treatment and medication given; the client's reaction; other health services provided; and any changes in physical and emotional condition.

(25) **CMS** ~ Centers for Medicare and Medicaid Services. The federal agency that administers the Medicare program and works in partnership with the states to administer Medicaid.

(26) **Complaint** ~ an allegation against an agency regulated by DADS or against an employee of an agency regulated by DADS that involves a violation of this chapter or the statute.

(27) **Community Disaster Resources** ~ a local, statewide, or nationwide emergency system that provides information and resources during a disaster, including weather information, transportation, evacuation, and shelter information, disaster assistance and recovery efforts, evacuee and disaster victim resources, and resources for locating evacuated friends and relatives.

(28) **Controlling Person** ~ a person with the ability, acting alone or with others, to directly or indirectly influence, direct, or cause the direction of the management, expenditure of money, or policies of an agency or other person.
(A) A controlling person includes:
   (i) a management company or other business entity that operates or contracts with others for the operation of an agency;
   (ii) a person who is a controlling person of a management company or other business entity that operates an agency or that contracts with another person for the operation of an agency; and
   (iii) any other individual who, because of a personal, familial, or other relationship with the owner, manager, or provider of an agency, is in a position of actual control or authority with respect to the agency, without regard to whether the individual is formally named as an owner, manager, director, officer, provider, consultant, contractor, or employee of the agency.
(B) A controlling person, as described by subparagraph (A)(iii) of this paragraph, does not include an employee, lender, secured creditor, or other person who does not exercise formal or actual influence or control over the operation of an agency.

(29) **Conviction** ~ an adjudication of guilt based on a finding of guilt, a plea of guilty, or a plea of nolo contendere.

(30) **Counselor** ~ an individual qualified under Medicare standards to provide counseling services, including bereavement, dietary, spiritual, and other counseling services to both the client and the family.

(31) **DADS** ~ Department of Aging and Disability Services.

(32) **Day** ~ any reference to a day means a calendar day, unless otherwise specified in the text. A calendar day includes weekends and holidays.

(33) **Deficiency** ~ a finding of noncompliance with federal requirements resulting from a survey.

(34) **Designated Survey Office** ~ a DADS HCSSA Program office located in an agency's geographic region.

(35) **Dialysis Treatment Record** ~ for home dialysis designation, a dated and signed written notation by the person providing dialysis treatment which contains a description of signs and symptoms, machine parameters and pressure settings, type of dialyzer and dialysate, actual pre- and post-treatment weight, medications administered as part of the treatment, and the client's response to treatment.

(36) **Dietitian** ~ a person who is currently licensed under the laws of the State of Texas to use the title of licensed dietitian or provisional licensed dietitian, or who is a registered dietitian.

(37) **Disaster** ~ the occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property resulting from a natural or man-made cause, such as fire, flood, earthquake, wind, storm, wave action, oil spill or other water contamination, epidemic, air contamination, infestation, explosion, riot, hostile military or paramilitary action, or energy emergency. In a freestanding hospice, a disaster also includes failure of the heating or cooling system, power outage, explosion, and bomb threat.

(38) **End Stage Renal Disease (ESRD)** ~ for home dialysis designation, the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

(39) **Freestanding Hospice** ~ an agency that provides hospice services to clients of the agency who are residing at the agency's physical location including inpatient and respite care.

(40) **Functional Need** ~ needs of the individual that require services without regard to diagnosis or label.

(41) **Health Assessment** ~ a determination of a client's physical and mental status through inventory of systems.

(42) **Home and Community Support Services Agency** ~ a person who provides home health, hospice, or personal assistance services for pay or other consideration in a client's residence, an independent living environment, or another appropriate location.

(43) **Home Health Aide** ~ an individual working for an agency who meets at least one of the requirements for home health aides as defined in §97.701.

(44) **Home Health Medication Aide** ~ a person permitted under the HSC Chapter 142 Subchapter B.

(45) **Home Health Service** ~ the provision of one or more of the following health services required by an individual in a residence or independent living environment:

- **A** nursing, including blood pressure monitoring and diabetes treatment;
- **B** physical, occupational, speech, or respiratory therapy;
- **C** medical social service;
- **D** intravenous therapy;
- **E** dialysis;
- **F** service provided by unlicensed personnel under the delegation or supervision of a licensed health professional;
(G) the furnishing of medical equipment and supplies, excluding drugs and medicines; or
(H) nutritional counseling.

(46) **Hospice** ~ a person licensed under this chapter to provide hospice services, including a person who owns or operates a residential unit or an inpatient unit.

(47) **Hospice Services** ~ services, including services provided by unlicensed personnel under the delegation of a registered nurse or physical therapist, provided to a client or a client's family as part of a coordinated program consistent with the standards and rules adopted under this chapter. These services include palliative care for terminally ill clients and support services for clients and their families that:
(A) are available 24 hours a day, seven days a week, during the last stages of illness, during death, and during bereavement;
(B) are provided by a medically directed interdisciplinary team; and
(C) may be provided in a home, nursing facility, residential unit, or inpatient unit according to need. These services do not include inpatient care normally provided in a licensed hospital to a terminally ill person who has not elected to be a hospice client. For the purposes of this definition, the word ‘home’ includes a person's ‘residence’ as defined in this section.

(48) **Independent Living Environment** ~ a client's residence, which may include a group home or foster home, or other settings where a client participates in activities, including school, work, or church.

(49) **Individual/Family Choice and Control** ~ individuals and families who express preferences and make choices about how their support service needs are met.

(50) **Individualized Service Plan** ~ a written plan prepared by the appropriate health care personnel for a client of a home and community support services agency licensed to provide personal assistance services.

(51) **Inpatient Unit** ~ a facility that provides a continuum of medical or nursing care and other hospice services to clients admitted into the unit and that is in compliance with:
(A) the conditions of participation for inpatient units adopted under SSA Title XVIII; and
(B) standards adopted under this chapter.

(52) **IRoD** ~ Informal Review of Deficiencies. An informal process that allows an agency to refute a deficiency or violation cited during a survey.

(53) **JCAHO** ~ Joint Commission on Accreditation of Healthcare Organizations. An independent, nonprofit organization for standard-setting and accrediting in-home care and other areas of health care.

(54) **Joint Training** ~ training provided by DADS at least semi-annually for home and community support services agencies and DADS surveyors on subjects that address the 10 most commonly cited violations of federal or state law by home and community support services agencies as published in DADS annual reports.

(55) **Licensed Vocational Nurse (LVN)** ~ a person who is currently licensed under Nursing Practice Act, Occupations Code, Chapter 301, as a licensed vocational nurse.


(57) **Manager** ~ an employee or independent contractor responsible for providing management services to a home and community support services agency for the overall operation of a home and community support services agency including administration, staffing, or delivery of services. Examples of contracts for services that will not be considered contracts for management services include contracts solely for maintenance, laundry, or food services.

(58) **Medication Administration Record** ~ a record used to document the administration of a client's medications.

(59) **Medication List** ~ a list that includes all prescription and over-the-counter medication that a client is currently taking, including the dosage, the frequency, and the method of administration.
Mitigation ~ an action taken to eliminate or reduce the probability of a disaster, or reduce a disaster's severity or consequences.

Notarized Copy ~ a sworn affidavit stating that attached copies are true and correct copies of the original documents.

Nursing Facility ~ an institution licensed as a nursing home under the HSC Chapter 242.

Nutritional Counseling ~ advising and assisting individuals or families on appropriate nutritional intake by integrating information from the nutrition assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status, with the goal being health promotion, disease prevention, and nutrition education. Nutritional counseling may include the following:
(A) dialogue with the client to discuss current eating habits, exercise habits, food budget, and problems with food preparation;
(B) discussion of dietary needs to help the client understand why certain foods should be included or excluded from the client's diet and to help with adjustment to the new or revised or existing diet plan;
(C) a personalized written diet plan as ordered by the client's physician or practitioner, to include instructions for implementation;
(D) providing the client with motivation to help the client understand and appreciate the importance of the diet plan in getting and staying healthy; or
(E) working with the client or the client's family members by recommending ideas for meal planning, food budget planning, and appropriate food gifts.

Occupational Therapist ~ a person who is currently licensed under the Occupational Therapy Practice Act, Occupations Code, Chapter 454, as an occupational therapist.

Operating Hours ~ the days of the week and the hours of day an agency place of business is open as identified in an agency's written policy as required by §97.210.

Original Active Client Record ~ a record composed first-hand for a client currently receiving services.

Palliative Care ~ intervention services that focus primarily on the reduction or abatement of physical, psychosocial, and spiritual symptoms of a terminal illness.

Parent Agency ~ an agency that develops and maintains administrative controls and provides supervision of branch offices and alternate delivery sites.

Parent Company ~ a person, other than an individual, who has a direct 100% ownership interest in the owner of an agency.

Person ~ an individual, corporation, or association.

Person with a Disclosable Interest ~ any person who owns at least a 5% interest in any corporation, partnership, or other business entity that is required to be licensed under HSC Chapter 142. A person with a disclosable interest does not include a bank, savings and loan, savings bank, trust company, building and loan association, credit union, individual loan and thrift company, investment banking firm, or insurance company, unless these entities participate in the management of the agency.

Personal Assistance Services (PAS) ~ routine ongoing care or services required by an individual in a residence or independent living environment that enable the individual to engage in the activities of daily living or to perform the physical functions required for independent living, including respite services. The term includes:
(A) personal care;
(B) health-related services performed under circumstances that are defined as not constituting the practice of professional nursing by the BON through a memorandum of understanding with DADS in accordance with HSC §142.016; and
(C) health-related tasks provided by unlicensed personnel under the delegation of a registered nurse or that a registered nurse determines do not require delegation.
Personal Care ~ the provision of one or more of the following services required by an individual in a residence or independent living environment:
  (A) bathing;
  (B) dressing;
  (C) grooming;
  (D) feeding;
  (E) exercising;
  (F) toileting;
  (G) positioning;
  (H) assisting with self-administered medications;
  (I) routine hair and skin care; and
  (J) transfer or ambulation.

Physical Therapist ~ a person who is currently licensed under Occupations Code, Chapter 453, as a physical therapist.

Physician ~ a person who holds a doctor of medicine or doctor of osteopathy degree and is currently licensed and practicing medicine under the laws of the state of Texas, Oklahoma, New Mexico, Arkansas, or Louisiana.

Physician Assistant ~ a person who is licensed under the Physician Assistant Licensing Act, Occupations Code, Chapter 204, as a physician assistant.

Physician-Delegated Task ~ a task performed in accordance with the Occupations Code, Chapter 157, including orders signed by a physician that specify the delegated task, the individual to whom the task is delegated, and the client's name.

Place of Business ~ an office of a HCSSA that maintains client records or directs home health, hospice, or PAS. This term includes a parent agency, a branch office, and an alternate delivery site. The term does not include an administrative support site.

Plan of Care ~ the written orders of a practitioner for a client who requires skilled services.

Practitioner ~ a person who is currently licensed in a state in which the person practices as a physician, dentist, podiatrist, or a physician assistant, or a person who is a registered nurse registered with the BON as an advanced practice nurse.

Preparedness ~ actions taken in anticipation of a disaster.

Presurvey Conference ~ a conference held with DADS staff and the applicant or the applicant's representatives to review licensure standards and survey documents, and to provide consultation before the survey.

Progress Note ~ a dated and signed written notation by agency personnel summarizing facts about care and the client's response during a given period of time.

Psychoactive Treatment ~ the provision of a skilled nursing visit to a client with a psychiatric diagnosis under the direction of a physician that includes one or more of the following:
  (A) assessment of alterations in mental status or evidence of suicide ideation or tendencies;
  (B) teaching coping mechanisms or skills;
  (C) counseling activities; or
  (D) evaluation of the plan of care.

Recovery ~ activities implemented during and after a disaster response designed to return an agency to its normal operations as quickly as possible.

Registered Nurse (RN) ~ a person who is currently licensed under the Nursing Practice Act, Occupations Code, Chapter 301, as a registered nurse.

Registered Nurse Delegation ~ delegation by a registered nurse in accordance with:
  (A) 22 TAC Chapter 224; and
  (B) 22 TAC Chapter 225.

Residence ~ a place where a person resides, including a home, a nursing facility, a convalescent home, or a residential unit.
(89) **Residential Unit** ~ a facility that provides living quarters and hospice services to clients admitted into the unit and that is in compliance with standards adopted under the HSC Chapter 142.

(90) **Respiratory Therapist** ~ a person who is currently licensed under Occupations Code, Chapter 604, as a respiratory care practitioner.

(91) **Respite Services** ~ support options that are provided temporarily for the purpose of relief for a primary caregiver in providing care to individuals of all ages with disabilities or at risk of abuse or neglect.

(92) **Response** ~ actions taken immediately before an impending disaster or during and after a disaster to address the immediate and short-term effects of the disaster.

(93) **Section** ~ a reference to a specific rule in this chapter.

(94) **Service Area** ~ a geographic area established by an agency in which all or some of the agency's services are available.

(95) **Skilled Services** ~ services in accordance with a plan of care that require the skills of:

   (A) a registered nurse;
   (B) a licensed vocational nurse;
   (C) a physical therapist;
   (D) an occupational therapist;
   (E) a respiratory therapist;
   (F) a speech-language pathologist;
   (G) an audiologist;
   (H) a social worker; or
   (I) a dietitian.

(96) **Social Worker** ~ a person who is currently licensed as a social worker under Social Work Practice Act, Occupations Code, Chapter 505.

(97) **Speech-Language Pathologist** ~ a person who is currently licensed as a speech-language pathologist under Occupations Code, Chapter 401.

(98) **Statute** ~ the Health and Safety Code, Chapter 142.

(99) **Substantial Compliance** ~ a finding in which an agency receives no recommendation for enforcement action after a survey.

(100) **Supervising Nurse** ~ the person responsible for supervising skilled services provided by an agency and who has the qualifications described in §97.244(c). This person may also be known as the director of nursing or similar title.

(101) **Supervision** ~ authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.

(102) **Support Services** ~ social, spiritual, and emotional care provided to a client and a client's family by a hospice.

(103) **Survey** ~ an on-site inspection or complaint investigation conducted by a DADS representative to determine if an agency is in compliance with the statute and this chapter or in compliance with applicable federal requirements or both.

(104) **Terminal Illness** ~ an illness for which there is a limited prognosis if the illness runs its usual course.

(105) **Unlicensed Person** ~ an individual who is not licensed as a health care professional. The term includes home health aides, medication aides permitted by DADS, and other individuals providing personal care or assistance in health services.

(106) **Unsatisfied Judgments** ~ a failure to fully carry out the terms or meet the obligation of a court's final disposition on the matters before it in a suit regarding the operation of an agency.

(107) **Violation** ~ a finding of noncompliance with this chapter or the statute resulting from a survey.

(108) **Volunteer** ~ an individual who provides assistance to a home and community support services agency without compensation other than reimbursement for actual expenses.

(109) **Working Day** ~ any day except Saturday, Sunday, a state holiday, or a federal holiday.
§97.3 ~ License Fees

(a) The schedule of fees for licensure of an agency authorized to provide one or more services is as follows:
   (1) Initial, including change of ownership, license fee ~ $1,750
   (2) Renewal license fee ~ $1,750
   (3) Initial branch office, including change of ownership, license fee ~ $1,750
   (4) Renewal branch office license fee ~ $1,750
   (5) Initial alternate delivery site, including change of ownership, license fee ~ $1,000
   (6) Renewal alternate delivery site license fee ~ $600

(b) The late fee established in §97.17 is one-half the amount of the required renewal license fee established in subsection (a) of this section plus the required renewal fee.

(c) If an applicant for an initial license based on a change of ownership submits a late application for a license to DADS, as described in §97.25, the applicant must pay the required initial license fee as set out in subsection (a) of this section plus a late fee of $250.

(d) DADS does not consider an application as officially submitted until the applicant pays the required license fee. The fee must accompany the application.

(e) A fee paid to DADS is not refundable, except as provided by §97.31.

(f) DADS accepts a certified check, money order, company check or personal check made out to DADS in payment for a required fee.

Subchapter B

§97.11 ~ Criteria and Eligibility for Licensing

(a) An applicant for a license must not admit a client or initiate services until the applicant completes the application process and receives an initial license.

(b) A first-time application for a license is an application for an initial license.

(c) An application for a license when there is a change of ownership is an application for an initial license.

(d) A separate license is required for each place of business as defined in §97.2.

(e) An agency's place of business must be located in and have an address in Texas. An agency located in another state must receive a license as a parent agency in Texas to operate as an agency in Texas.

(f) An applicant must be at least 18 years of age.

(g) Before issuing a license, DADS considers the background and qualifications of:
   (1) the applicant;
   (2) a controlling person of the applicant;
   (3) a person with a disclosable interest;
   (4) an affiliate of the applicant;
   (5) the administrator;
   (6) the alternate administrator; and
   (7) the chief financial officer.

(h) DADS may deny an application for an initial license or for renewal of a license if any person described in subsection (g) of this section:
   (1) on the date of the application:
      (A) is subject to denial or refusal as described in Chapter 99 during the time frames described in that chapter;
      (B) has an unsatisfied final judgment in any state or other jurisdiction;
      (C) is in default on a guaranteed student loan (Education Code, §57.491); or
      (D) is delinquent on child support obligations (Family Code, Chapter 232);
   (2) for two years preceding the date of the application, has a history in any state or other jurisdiction of any of the following:
      (A) an unresolved federal or state tax lien;
(B) an eviction involving any property or space used as an inpatient hospice agency; or
(C) an unresolved final Medicare or Medicaid audit exception; or

(3) for twelve months preceding the date of the application, has a history in any state or other jurisdiction of any of the following:
   (A) denial, suspension, or revocation of an agency license or a license for a health care facility;
   (B) surrendering a license before expiration or allowing a license to expire instead of the licensing authority proceeding with enforcement action;
   (C) a Medicaid or Medicare sanction or penalty relating to the operation of an agency or a health care facility;
   (D) operating an agency that has been decertified in any state under Medicare or Medicaid; or
   (E) debarment, exclusion, or involuntary contract cancellation in any state from Medicare or Medicaid.

§97.13 ~ APPLICATION PROCEDURES FOR AN INITIAL LICENSE

(a) The following staff must complete a presurvey conference seminar before submitting an application for a license:
   (1) the administrator and alternate administrator (all license categories); and
   (2) the supervising nurse and alternate supervising nurse (LHHS with or without home dialysis designation, LCHHS with or without home dialysis designation, and Hospice Services license categories).

(b) When applying for a license, an applicant must not:
   (1) provide incorrect or false information; or
   (2) withhold information.

(c) Upon request, DADS furnishes a person with an application packet for a license.

(d) An applicant may request to be licensed in one or more of the following categories:
   (1) Licensed and Certified Home Health Services (LCHHS);
   (2) Licensed and Certified Home Health Services with home Dialysis designation (LCHHS-D);
   (3) Licensed Home Health Services (LHHS);
   (4) Licensed Home Health Services with home Dialysis designation (LHHS-D);
   (5) Hospice Services; or
   (6) Personal Assistance Services (PAS).

(e) DADS does not require an agency to be licensed in more than one category if the category for which the agency is licensed covers the services the agency provides.

(f) An applicant must complete and furnish all documents and information that DADS requests in accordance with instructions provided with the application packet. All submitted documents must be notarized copies or originals.

(g) Upon receipt of an application packet and license fee, DADS reviews the material to determine whether it is complete and correct. A complete and correct application packet includes all documents and information that DADS requests as part of the application process. If DADS receives a partial fee, the application packet and monies are returned to the applicant.
   (1) DADS processes the application packet in accordance with time frames established in §97.31.
   (2) If an applicant decides not to continue the application process for an initial license after submitting the application packet and license fee, the applicant must submit to DADS a written request to withdraw the application. DADS does not refund the license fee.
   (3) If an applicant receives a notice from DADS that some or all of the information required by this section is missing or incomplete, the applicant must submit the required information no later than 30 days after the date of the notice. If an applicant fails to submit the required information within 30 days after the notice date, DADS considers the application packet incomplete and denies the application. If DADS denies the application, DADS does not refund the license fee.

(h) An applicant who has requested the category of LCHHS on the initial license application must also make an application for certification by CMS as a Medicare-certified agency under the SSA Title XVIII.
(1) Pending approval by CMS, the applicant:
   (A) receives an initial license reflecting the category of LHHS if the applicant meets the criteria for a license; and
   (B) complies with the Medicare conditions of participation for home health agencies in 42 Code of Federal Regulations (CFR), Part 484, as if the applicant were dually certified.

(2) If CMS certifies an agency to participate in the Medicare program during the initial license period, DADS sends a notice to the agency that the category of LCHHS has been added to the license. If the agency wants to delete the LHHS category once the category of LCHHS has been added, the agency must submit a written request for deletion of that category.

(3) If CMS denies certification to an applicant or if the applicant withdraws the application for participation in the Medicare program, the agency may retain the category of LHHS.

§97.15 ~ ISSUANCE OF AN INITIAL LICENSE
(a) DADS issues an initial license when DADS determines:
   (1) an application and license fee are complete and correct; and
   (2) an applicant meets the criteria for a license as described in §97.11.
(b) An initial license is valid for two years from the date of issuance.
(c) DADS may deny an application to renew an initial license, or revoke or suspend an initial license, if an agency fails to:
   (1) meet the requirements for an initial survey as specified in Subchapter E; or
   (2) maintain substantial compliance with the statute and this chapter for the services authorized under the license.
(d) DADS may deny an application for an initial license for any of the reasons specified in §97.21.
(e) A license designates an agency's place of business from which services are to be provided and designates an agency's authorized category or categories of service.

§97.17 ~ APPLICATION PROCEDURES FOR A RENEWAL LICENSE
(a) An agency license is valid for two years. In order to continue providing services to clients, an agency must renew its license.
(b) When applying for a renewal license, an agency must not provide inaccurate or false statements or withhold information from the renewal application and attachments to the application. If an agency provides inaccurate or false statements or withholds information from a renewal application or an attachment to the application, DADS may assess the same range of penalties against the agency that apply in §97.13 for providing inaccurate or false statements or withholding information from an initial application for a license.
(c) For each license period, an agency must provide services to at least one client.
(d) DADS does not require an agency to admit a client under each category of service authorized under the license as a condition for renewal of the license.
(e) An agency must document the provision of services and keep documentation readily available for review by a DADS surveyor.
(f) With each renewal application, an accredited agency must submit documentation of its accreditation that the agency receives from the accreditation organization.
(g) DADS sends written notice of expiration of a license to an agency at least 120 days before the expiration date of the license. The written notice includes an application to renew the license and instructions for completing the application.
   (1) If an agency does not receive notice of expiration from DADS at least 90 days before the expiration date of a license, the agency must notify DADS and submit a written request for a renewal application.
   (2) An agency must submit to DADS a complete and correct renewal application and the required license fee specified in §97.3, postmarked no later than the 45th day before the expiration date of the license.
(3) If an agency submits a renewal application that is postmarked later than the 45th day before the expiration date of a license, but no later than the expiration date of the license, DADS assesses the late fee set out in §97.3(b) for failure to comply with paragraph (2) of this subsection.

(4) All documents submitted with the renewal application must be notarized copies or originals.

(h) Upon receipt of a renewal application and the renewal license fee, DADS reviews the application to determine whether it is complete and correct. A complete and correct renewal application includes all documents, information, and the required fee that DADS requests as part of the application process.

(1) DADS processes the renewal application according to the time frames in §97.31.

(2) If an agency decides to discontinue the application process for a renewal license after submitting the renewal application and the renewal license fee, the agency must submit to DADS a notarized statement requesting to withdraw the renewal application. DADS does not refund the renewal license fee.

(3) DADS notifies an agency, in writing, if an application does not include all documents, information, or the license fee required by this section. An agency must submit the missing documents, information, or fee to DADS postmarked no later than 30 days after the date of the notice or DADS considers the renewal application incomplete and denies the application. If DADS denies the renewal application, DADS does not refund the renewal license fee.

(4) If an agency receives a written notice from DADS that a late fee is assessed in accordance with subsection (g) of this section, the agency's late fee must be postmarked no later than 30 days after the date of the notice or DADS considers the renewal application incomplete and denies the application. If DADS denies the renewal application, DADS does not refund the renewal license fee.

(i) If an agency submits a renewal application to DADS that is postmarked after the expiration date of the license, DADS denies the renewal application and does not refund the renewal license fee. The agency is not eligible to renew the license and must cease operation on the date the license expires. An agency whose license expires must apply for an initial license in accordance with §97.13.

(j) If an agency submits a timely renewal application in accordance with this section, and an action to revoke, suspend, or deny renewal of the license is pending, the agency may continue to operate, and the license is valid until the agency has had an opportunity for a formal hearing as described in §97.601. Until the action to revoke, suspend, or deny renewal of the license is completed, the agency must continue to submit a renewal application in accordance with this section. DADS issues a renewal license only if DADS determines the reason for the proposed action no longer exists.

(k) If a license holder fails to submit a timely renewal application in accordance with this section because the license holder is or was on active duty with the armed forces of the United States of America outside the state of Texas, the license holder may renew the license pursuant to this subsection.

(1) An individual having power of attorney from the license holder or other authority to act on behalf of the license holder may request renewal of the license. The renewal application must include a current address and telephone number for the individual requesting the renewal.

(2) An agency may request a renewal application before or after the expiration of the license.

(3) A copy of the official orders or other official military documentation showing that the license holder is or was on active military duty serving outside the state of Texas must be filed with DADS along with the renewal application.

(4) A copy of the power of attorney from the license holder or other authority to act on behalf of the license holder must be filed with DADS along with the renewal application.

(5) A license holder renewing under this subsection must pay the applicable renewal fee.

(6) A license holder is not authorized to operate the agency for which the license was obtained after the expiration of the license unless and until the license holder actually renews the license.

(7) This subsection applies to a license holder who is an individual or a partnership comprised of individuals, all of whom are or were on active duty with the armed forces of the United States of America serving outside the state of Texas.
§97.19 ~ Issuance of a Renewal License
(a) A renewal license is valid for two years. The new licensure period begins the day after the previous license expires.
(b) Except as specified in §97.503, DADS may not renew an initial license unless DADS conducts an initial survey of the agency. For renewal of an initial license, an agency must:
   (1) meet the requirements for an initial survey as specified in Subchapter E;
   (2) demonstrate substantial compliance with the statute and this chapter for the services authorized under the license as confirmed by an initial survey; and
   (3) apply for renewal of the license in accordance with §97.17.
(c) For renewal of a license other than an initial license, an agency must:
   (1) maintain substantial compliance with the statute and this chapter for the services authorized under the license; and
   (2) apply for renewal of the license in accordance with §97.17.
(d) DADS may deny a renewal application:
   (1) if an agency fails to meet the eligibility criteria in §97.11;
   (2) if the agency fails to meet the requirements for renewal of a license as specified in this section; or
   (3) for any of the reasons specified in §97.21.
(e) A renewal license designates an agency's place of business from which services are to be provided and designates an agency's authorized category or categories of service.

§97.21 ~ Denial of an Application or a License
(a) DADS may deny an application for an initial license or for renewal of a license if any person described in §97.11(g):
   (1) fails to comply with the statute;
   (2) fails to comply with this chapter;
   (3) knowingly aids, abets, or permits another person to violate the statute or this chapter;
   (4) fails to meet the criteria for a license established in §97.11 of this subchapter; or
   (5) violates Occupations Code, §102.001 or §102.006.
(b) If DADS denies an application for an initial license or for renewal of a license, the applicant or agency may request an administrative hearing in accordance with §97.601.

§97.23 ~ Change of Ownership
(a) A license issued under this chapter may not be sold or assigned to another person.
(b) A change of ownership occurs when there is:
   (1) a change of 50% or more in the ownership of the business organization or sole proprietorship that is licensed to operate the agency; or
   (2) a change in the federal taxpayer identification number.
(c) A change of ownership for a parent agency is a change of ownership for the parent agency's branch office or alternate delivery site and requires the submittal of an initial application and license fee for the branch office or alternate delivery site.
(d) A change of ownership does not apply if an agency is a business entity and is simply amending its official documents to revise its name.
(e) For agencies licensed to provide LCHHS and licensed and certified hospice services, applicable federal laws and regulations relating to change of ownership or control apply in addition to the requirements of this section.

§97.25 ~ Application Procedures and Requirements for Change of Ownership
(a) An application for an initial license resulting from a change of ownership must be requested at least 60 days before the effective date of the change of ownership.
   (1) To avoid a gap in the license period, a prospective new owner must submit a complete and correct application packet for a license and the appropriate license fee to DADS at least 30 days before the anticipated date of sale or other transfer of ownership, and before expiration date of the license.
(2) An applicant must submit a complete and correct application packet to DADS in accordance with the instructions provided with the application packet.

(3) An applicant must meet the criteria for a license as described in §97.11.

(4) If an applicant submits a timely and sufficient application packet and license fee and meets all criteria for a license, DADS issues the applicant a license effective on the date of the transfer of ownership. DADS considers an applicant to have filed a timely and sufficient application for a license if the applicant submits:

(A) a complete and correct application packet and license fee to DADS that is postmarked at least 30 days before the anticipated date of sale or other transfer of ownership, and before the expiration date of the license;

(B) an incomplete application packet and license fee to DADS with a letter explaining the circumstances that prevented its completion that is postmarked at least 30 days before the anticipated date of sale or other transfer of ownership, and before the expiration date of the license; and DADS accepts the explanation. The applicant must submit the missing information to DADS within 30 days after the date of the letter;

(C) a complete and correct application packet and license fee to DADS that is postmarked less than 30 days before the anticipated date of sale or other transfer of ownership, and before the expiration date of the license; and the applicant pays the late fee set out in §97.3(d); or

(D) a complete and correct application packet and license fee to DADS that is received by the date of sale or other transfer of ownership, and before the expiration date of the license; and the applicant proves to DADS' satisfaction that the health and safety of the agency's clients required an emergency change of ownership.

(5) If an applicant files a timely application packet and license fee, but DADS determines that the application packet is incomplete and a letter explaining the circumstances that prevented its completion was not filed with the application, DADS considers the application timely filed but incomplete.

(A) DADS provides the applicant with written notification of the missing information required to complete the application and may assess the late fee set out in §97.3(d) for failure to comply with paragraph (1) of this subsection.

(B) An applicant must submit the required information and late fee, if assessed, no later than 30 days after the date of the notice. If an applicant fails to submit the required information within 30 days after the notice date, DADS considers the application incomplete and DADS denies the license. If DADS denies the license, DADS does not refund the license fee.

(6) The initial license issued to the new owner is valid for two years from the date of issuance.

(7) The previous owner's license is void on the effective date of the new owner's initial license. The previous owner's license must be surrendered to DADS within five working days after the effective date of the change of ownership.

(8) DADS may deny issuance of a license for any of the reasons specified in §97.21.

(b) For agencies licensed to provide LCHHS and licensed and certified hospice services, applicable federal laws and regulations relating to change of ownership or control apply in addition to the requirements of this section.

§97.27 ~ Application and Issuance of a Branch Office License

(a) An agency with a current license to provide LHHS, LCHHS, or PAS may qualify for a branch office license if the parent agency:

(1) is found to be in substantial compliance with the statute and this chapter; and

(2) has no enforcement action pending against the license.

(b) Upon request, DADS furnishes a parent agency with an application packet for a branch office license.

(c) An agency must submit to DADS a complete and correct application packet and the required license fee for a branch office license in accordance with the instructions provided with the application packet. A complete and correct application packet includes all documents and information that DADS requests as part of the application process.
(d) DADS reviews an application packet for a branch office license to determine whether it is complete and correct.
   (1) DADS processes an application packet for a branch office license according to the time frames in §97.31.
   (2) If an agency receives a notice from DADS that some or all of the information required by this section is missing or incomplete, the agency must submit the required information no later than 30 days after the date of the notice. If an agency fails to submit the required information within 30 days after the notice date, DADS considers the application for a branch office license incomplete and denies the application. If DADS denies the application, DADS does not refund the license fee.

(e) A designated survey office conducts a review of an agency's request to establish a branch office. The survey office makes a recommendation to approve or disapprove the branch office request.

(f) DADS approves or denies the application for a branch office license after considering the designated survey office's recommendation. If DADS denies the application, DADS sends the agency a written notice:
   (1) informing the agency of its decision; and
   (2) providing the agency with an opportunity to appeal its decision through a formal hearing process as described in §97.601.

(g) CMS approves or denies the branch location if an agency is licensed to provide LCHHS.

(h) A branch office license expires on the same expiration date as the parent agency's license, and the agency may renew it with the parent agency's license.

(i) DADS mails the branch office license to the parent agency. The branch office must post the license in a conspicuous place on the licensed branch office premises.

(j) A branch office must comply with §97.321 and the additional standards that relate to the agency's authorized categories under the license.

(k) DADS may conduct a survey of a branch office after issuance of the license to verify compliance with the statute and this chapter.

§97.29 ~ Application and Issuance of an Alternate Delivery Site License

(a) An agency with a current license to provide hospice services may qualify for an alternate delivery site license if the parent agency:
   (1) is found to be in substantial compliance with the statute and this chapter; and
   (2) has no enforcement action pending against the license.

(b) Upon request, DADS furnishes a parent agency with an application packet for an alternate delivery site license.

(c) An agency must submit to DADS a complete and correct application packet and the required license fee for an alternate delivery site in accordance with instructions provided with the application packet. A complete and correct application packet includes all documents and information that DADS requests as part of the application process.

(d) DADS reviews an application packet for an alternate delivery site to determine whether it is complete and correct.
   (1) DADS processes an application packet for an alternate delivery site according to the time frames in §97.31.
   (2) If an agency receives a notice from DADS that some or all of the information required by this section is missing or incomplete, the agency must submit the required information no later than 30 days after the date of the notice. If an agency fails to submit the required information within 30 days after the notice date, DADS considers the application for an alternate delivery site license incomplete and denies the application. If DADS denies the application, DADS does not refund the license fee.

(e) A designated survey office conducts a review of an agency's request to establish an alternate delivery site. The survey office makes a recommendation to approve or deny the alternate delivery site request.
(f) If an agency provides licensed-only hospice services, DADS approves or denies the application for an alternate delivery site after considering the designated survey office’s recommendation. If DADS denies the application, DADS sends the agency a written notice:
   (1) informing the agency of its decision; and
   (2) providing the agency with an opportunity to appeal its decision through a formal hearing process as described in §97.601.

(g) CMS approves or denies the alternate delivery site if an agency is licensed to provide licensed and certified hospice services.

(h) An alternate delivery site license expires on the same expiration date as the parent agency’s license, and the agency may renew it with the parent agency’s license.

(i) DADS mails an alternate delivery site license to the parent agency. The alternate delivery site must post the license in a conspicuous place on the licensed alternate delivery site premises.

(j) An alternate delivery site must comply with §97.403 and §97.322.

(k) The designated survey office conducts a survey after issuance of the license to verify compliance with §97.403 and §97.322.

(l) The designated survey office may recommend that a licensed alternate delivery site seek a license as a parent agency, under but not exclusive of the following conditions:
   (1) the alternate delivery site is the hospice’s principal place of business as defined in §97.2; or
   (2) the alternate delivery site is located outside the geographical area served by the parent agency.

§97.31 ~ TIME FRAMES FOR PROCESSING AND ISSUING A LICENSE
(a) General.
   (1) In this section, the date of an application is the date the DADS HCSSA Licensing Unit receives the application.
   (2) DADS considers an application for an initial license complete when DADS receives, reviews, and accepts the information described in §97.13.
   (3) DADS considers an application for a renewal license complete when DADS receives, reviews, and accepts the information described in §97.17. An agency may continue to operate in accordance with §97.17(j).
   (4) DADS considers an application for a change of ownership license complete when DADS receives, reviews, and accepts the information described in §97.25.
   (5) DADS considers an application for a branch office license complete when DADS receives, reviews, and accepts the information described in §97.27.
   (6) DADS considers an application for an alternate delivery site license complete when DADS receives, reviews, and accepts the information described in §97.29.

(b) Time frames. An application from an agency for an initial, renewal, change of ownership, branch office, or alternate delivery site license is processed in accordance with the following time frames:
   (1) The first time frame begins on the date DADS HCSSA Licensing Unit receives an application and ends on the date a license is issued. If DADS HCSSA Licensing Unit receives an incomplete application, the first time frame ends on the date DADS HCSSA Licensing Unit sends a written notice to the agency that the application is incomplete. The written notice describes the specific information that the applicant must submit to complete the application. The first time frame is no longer than 45 days.
   (2) The second time frame begins on the date DADS HCSSA Licensing Unit receives the last item necessary to complete the application and ends on the date the license is issued. The second time frame is no longer than 45 days.
   (3) If an agency is subject to a proposed or pending enforcement action on its license on or within 45 days before the expiration date of the license, DADS may suspend issuance of a renewal license until a formal hearing as described in §97.601 is complete.
(c) Reimbursement of fees.
   (1) If DADS does not process the application in the time frames stated in subsection (b) of this
   section, the applicant has the right to request that DADS reimburse the license fee. If DADS does
   not agree that the established time frames have been violated or finds that good cause existed for
   exceeding the established time frames, DADS denies the request.
   (2) DADS considers that good cause for exceeding the established time frames exists if:
      (A) the number of applications to be processed exceeds by 15% or more the number of
          applications processed in the same quarter for the preceding year;
      (B) another public or private entity used in the application process caused the delay; or
      (C) other conditions existed giving good cause for exceeding the established time frames.
   (d) Appeal. If DADS denies the request for reimbursement of the license fee as authorized by subsection
   (c) of this section, the applicant may appeal the denial. In order to appeal, the applicant must send a
   written request for reimbursement of the license fee to the DADS commissioner. The request must
   include that the application was not processed within the established time frame. DADS HCSSA
   Licensing Unit provides the DADS commissioner with a written report of the facts related to the
   processing of the application and good cause for exceeding the established time frame. The DADS
   commissioner makes the final decision and provides written notification of the decision to the
   applicant and DADS HCSSA Licensing Unit.

SUBCHAPTER C
DIVISION 1
§97.201 ~ APPLICABILITY
(a) This subchapter applies to a home and community support services agency providing LHHS or
    LCHHS with and without home dialysis designation, hospice services, or PAS.
(b) In addition to the minimum standards in this subchapter, an agency must also comply with applicable
    standards in Subchapter D.

DIVISION 2
§97.208 ~ REPORTING CHANGES IN APPLICATION INFORMATION AND FEES
(a) If certain information provided on an initial or renewal application changes after DADS issues the
    license, an agency must report the change to DADS. The agency must use the HCSSA License
    Application, DADS Form 2021, to report the change. To avoid a late fee, a change must be reported
    within the time frame specified for the type of change.
   (1) For requirements on reporting a change in the agency’s location, see §97.213;
   (2) For requirements on reporting a change in the agency’s contact information and operating hours,
       see §97.214;
   (3) For requirements on reporting a change to the agency’s name, see §97.215;
   (4) For requirements on reporting a change in the agency’s organizational management personnel,
       see §97.218;
   (5) For requirements on adding or deleting a category of service to the license, see §97.219; and
   (6) For requirements on expanding or reducing the agency’s service area, see §97.220.
(b) The schedule of fees an agency must pay when the agency timely submits DADS Form 2021 to
    report changes in application information is as follows.
   (1) An agency is not required to pay a fee if the agency reports changes to contact information and
       operating hours, within the required time frame, as specified in §97.214.
   (2) An agency is not required to pay a fee if the agency reports a change in the alternate
       administrator, within the required time frame, as specified in §97.218.
   (3) An agency must pay a fee of $30 if the agency, within the required time frame, reports one or
       more of the following changes:
       (A) a change in physical location, as specified in §97.213;
       (B) a change in name (legal entity or doing business as), as specified in §97.215;
(C) a change in administrator, chief financial officer or controlling person, as specified in §97.218;
(D) a change in category of service designated on a license, as specified in §97.219; or
(E) a change in service area, as specified in §97.220.

(c) If an agency untimely submits DADS Form 2021 to report one or more changes referenced in subsection (a) of this section, the agency must pay a late fee of $100. If an agency must pay a fee of $30 for reporting a change referenced in subsection (b)(3) of this section, the $100 late fee is in addition to the $30 fee.

(d) If DADS determines, based on review of an agency's renewal application, that an agency did not report a change in application information as required by this section, DADS notifies the agency in writing of the fee amount due for payment.

(e) If DADS determines, based on a survey, that an agency did not report a change in application information as required by this section, DADS notifies the agency in writing of the fee amount due for payment. Reporting the change and paying the required fee does not preclude DADS from taking other enforcement action against the agency as specified in §97.601.

(f) If an agency pays a fee to DADS to report a change in application information, the fee is not refundable. DADS accepts payment for a required fee as described in §97.3(f).

(g) DADS may suspend or revoke a license or deny an application for a renewal license if an agency does not pay a fee as required by this section within 30 days after DADS provides written notice of a fee amount due for payment. Within 10 days after receipt of DADS written notice of a fee amount due for payment, an agency may submit proof to DADS that the agency:
   (1) submitted DADS Form 2021 to timely report a change in application information as specified in each rule referenced in subsection (a) of this section; or
   (2) paid the fee amount required by this section when the agency submitted DADS Form 2021.

§97.210 ~ AGENCY OPERATING HOURS
(a) An agency must adopt and enforce a written policy identifying the agency's operating hours.
(b) For the purposes of this section, the person in charge means the administrator, the designated alternate administrator, the supervising nurse, or the alternate supervising nurse.
(c) If an agency is closed during the agency's operating hours or between the hours of 8:00 am and 5:00 pm Monday through Friday, the person in charge must:
   (1) post a notice in a visible location outside the agency that will provide information regarding how to contact the person in charge; and
   (2) leave a message on an answering machine or similar electronic mechanism that will provide information regarding how to contact the person in charge.

§97.210 ~ DISPLAY OF LICENSE
The license must be displayed in a conspicuous place in the designated place of business. If the information on the license is officially amended during the licensure period, a notice must be posted beside the license to provide public notice of the change.

§97.212 ~ LICENSE ALTERATION PROHIBITED
A license may not be altered.

§97.213 ~ AGENCY RELOCATION
(a) An agency must not transfer a license from one location to another without prior notice to DADS. If an agency is considering relocation, the agency must submit written notice to DADS to report a change in physical location at least 30 days before the intended relocation unless DADS grants the agency an exemption from the 30-day time frame as specified in subsection (b) of this section. A change in physical location for a hospice inpatient unit requires DADS to conduct a survey to approve the new location.
(b) An agency must notify DADS immediately if an unexpected situation beyond the agency’s control makes it impossible for the agency to submit written notice to DADS no later than 30 days before the agency relocates. DADS grants or denies the exemption.

(1) If DADS grants the exemption, the agency must submit written notice to DADS as described in subsection (c) of this section within 30 days after the date DADS grants the exemption.

(2) If DADS denies the exemption, the agency may not relocate until at least 30 days after the agency submits the written notice to DADS as described in subsection (c) of this section.

(c) An agency must use the HCSSA License Application, DADS Form 2021, to submit the written notice and follow the instructions on the DADS website for reporting a change in physical location.

(d) If an agency reports a change in physical location, the agency must pay a fee and may be subject to a late fee, as described in §97.208.

(e) DADS sends the agency a Notification of Change reflecting the new location. The agency must post the Notification of Change beside its license in accordance with §97.211.

(f) A Medicare certified home health and hospice agency must comply with applicable federal laws and regulations and the requirements of this section for reporting an agency relocation. A change in physical location for a Medicare-certified agency requires DADS review.

(g) An agency is exempt from the requirements in subsections (a) - (d) of this section when reporting a temporary relocation that results from the effects of an emergency or disaster, as specified in §97.256(o).

§97.214 ~ Notification Procedures for a Change in Agency Contact Information and Operating Hours

(a) An agency must submit written notice to DADS no later than seven days after a change in the agency’s:

(1) telephone number; or

(2) mailing address, if different than the physical location.

(b) An agency must notify DADS no later than seven days after a change in the agency’s operating hours.

(c) An agency must use the HCSSA License Application, DADS Form 2021, to submit the written notice and follow the instructions on DADS website for reporting the changes described in subsections (a) and (b) of this section.

(d) If an agency reports the information after the timeframes required by this section, the agency must pay a late fee as described in §97.208.

§97.215 ~ Notification Procedures for an Agency Name Change

(a) If an agency intends to change its name (legal entity or doing business as), but does not undergo a change of ownership as defined in §97.23(b), the agency must report the name change to DADS no later than seven days after the effective date of the name change.

(b) An agency must use the HCSSA License Application, DADS Form 2021, to submit the written notice and follow the instructions on DADS website for reporting a name change.

(c) If an agency reports a name change, the agency must pay a fee and may be subject to a late fee, as described in §97.208.

(d) After DADS receives and verifies the required documents and information, DADS sends the agency a Notification of Change reflecting the agency’s new name. The agency must post the Notification of Change beside its license in accordance with §97.211.

§97.216 ~ Change in Agency Certification Status

(a) An agency must notify DADS in writing no later than five days after the agency decides to voluntarily withdraw from the Medicare Program. If an agency’s voluntary withdrawal from the Medicare Program is based on the permanent closure of the agency, the agency must also comply with §97.217.
(b) If an agency chooses to voluntarily withdraw from the Medicare Program, or if CMS involuntarily terminates or denies its certification, the license will be affected as follows:
  (1) If an agency licensed to provide licensed and certified home health services has no other license categories remaining on the license after losing its Medicare certification, its license is void and the agency must cease operation. If the agency wants to resume providing services, it must apply for an initial license.
  (2) If a Medicare-certified agency has another license category remaining on the current license and the agency wants to continue providing services under the remaining license category, DADS surveys the agency under the remaining license category.
(c) As specified in §97.601(c)(2), DADS may take enforcement action against an agency licensed to provide licensed and certified home health services if the agency fails to maintain its Medicare certification. The agency may request an administrative hearing in accordance with §97.601 of to contest the enforcement action taken by DADS against the agency.

§97.217 ~ Agency Closure Procedures and Voluntary Suspension of Operations
(a) Permanent closure. An agency must notify DADS in writing within five days before the permanent closure of the agency, branch office, or alternate delivery site.
  (1) The agency must include in the written notice the reason for closing, the location of the client records (active and inactive), and the name and address of the client record custodian.
  (2) If the agency closes with an active client roster, the agency must transfer a copy of the active client record with the client to the receiving agency in order to ensure continuity of care and services to the client.
  (3) The agency must mail or return the initial license or renewal license to DADS at the end of the day that services ceased.
  (4) If an agency continues to operate after the closure date specified in the notice, DADS may take enforcement action against the agency.
(b) Applicability. This subsection applies to an agency licensed to provide licensed home health services, personal assistance services, and licensed-only hospice services.
  (1) Voluntary suspension of operations occurs when an agency voluntarily suspends its normal business operations for 10 or more consecutive days. A voluntary suspension of operations may not last longer than the licensure renewal period. If an agency voluntarily suspends operations, the agency must:
    (A) discharge or arrange for backup services for active clients;
    (B) provide written notification to the designated survey office at least five days before the voluntary suspension of operations or within two working days before the voluntary suspension of operations if an emergency occurs that is beyond the agency’s control; and
    (C) post a notice of voluntary suspension of operations on the entry door of the agency and leave a message on an answering machine or with an answering service that informs callers of the voluntary suspension of operations.
  (2) An agency must notify the HCSSA Licensing Unit in writing no later than seven days after resuming operations.

§97.218 ~ Agency Organizational Changes
(a) If a change occurs in the following management personnel, an agency must submit written notice to DADS no later than seven days after the date of a change in:
  (1) administrator;
  (2) alternate administrator;
  (3) chief financial officer; or
  (4) controlling person, as defined in §97.2.
(b) An agency must use the HCSSA License Application, DADS Form 2021, to submit the written notice and follow the instructions on DADS website for reporting a change in the management personnel listed in subsection (a) of this section.
(c) If an agency reports a change in the administrator, chief financial officer or controlling person, the agency must pay a fee and may be subject to a late fee, as described in §97.208.

(d) An agency is not required to pay a fee to report a change in alternate administrator, but the agency must pay a late fee, as described in §97.208, if the agency does not report the change within the time frame required in this section.

(e) A change in the management personnel listed in subsection (a) of this section requires DADS evaluation and approval. DADS reviews the required documents and information submitted. DADS notifies an agency if the information the agency provides does not reflect that a person listed in subsection (a)(1) - (4) of this section meets the required qualifications.

§97.219 ~ PROCEDURES FOR ADDING OR Deleting A CATEGORY TO THE LICENSE

(a) To add or delete a category of service to a license, an agency must submit written notice to DADS at least 30 days before the addition or deletion of the category.

(b) DADS either approves or denies the addition of a category of service no later than 30 days after DADS receives the written notice. An agency must not provide the services under the category the agency is adding until the agency receives written notice of approval from DADS.

(1) To add a category of service to a license, an agency must:
   (A) be in substantial compliance with the statute and this chapter; and
   (B) have no enforcement action pending against the license.

(2) If DADS denies the addition of a category of service, DADS informs the agency of the reason for denial.

(3) DADS may conduct a survey after the approval of a category.

(c) DADS receipt of a request to delete a category from a license does not preclude DADS from taking enforcement action as appropriate in accordance with Subchapter F.

(d) An agency must use the HCSSA License Application, DADS Form 2021, to submit the written notice and follow the instructions on DADS website for requesting to add or delete a category of service.

(e) If an agency reports a change in a category of service, the agency must pay a fee and may be subject to a late fee, as described in §97.208.

(f) When DADS adds or deletes a category of service, DADS sends the agency a Notification of Change reflecting the change in the category of service. The agency must post the Notification of Change beside its license in accordance with §97.211.

§97.220 ~ SERVICE AREAS

(a) An agency must identify its licensed service area. A branch office or alternate delivery site must be located within the parent agency’s licensed service area. An agency must not provide services outside its licensed service area.

(b) An agency must maintain adequate staff to provide services and to supervise the provision of services within its licensed service area.

(c) An agency may expand its service area at any time during the licensure period. An agency must submit written notice to DADS to expand the agency’s service area at least 30 days before the expansion unless DADS grants the agency an exemption from the 30-day time frame as specified in subsection (d) of this section.

(d) An agency is exempt from the requirement to submit written notice to DADS no later than 30 days before the agency expands its service area if DADS determines an emergency situation exists that would affect client health and safety.

(1) An agency must notify DADS immediately of a possible emergency situation that would affect client health and safety.

(2) DADS grants or denies an exemption from the 30-day written notice requirement.
   (A) If DADS grants an exemption, the agency must submit written notice to DADS, as described in subsection (e) of this section, no later than 30 days after the date DADS grants the exemption.
(B) If DADS denies an exemption, the agency may not expand agency's service area until at least 30 days after the agency submits the written notice to DADS as described in subsection (e) of this section.

(e) If an agency intends to expand or reduce the agency's service area, the agency must submit written notice to DADS by using the HCSSA License Application, DADS Form 2021, following the instructions on the DADS website for requesting to expand or reduce the agency's service area.

(f) If an agency reports a change in service area, the agency must pay a fee and may be subject to a late fee, as described in §97.208.

(g) An agency may reduce its service area at any time during the licensure period. An agency must submit written notice to DADS informing DADS that the agency reduced its service area no later than 10 days after the reduction.

(h) DADS sends the agency a Notification of Change reflecting the change in service area. An agency is not required to post the Notification of Change in service area beside its license.

(i) An agency is exempt from the requirements described in subsections (c) - (f) of this section if a temporary expansion results from an emergency or disaster, as specified in §97.256(o).

§97.222 ~ COMPLIANCE
An agency must maintain satisfactory compliance with all the provisions of the statute and this chapter to maintain licensure.

DIVISION 3
§97.241 ~ MANAGEMENT
(a) Agency policies. The license holder is responsible for the conduct of the agency and for the adoption, implementation, enforcement, and monitoring of adherence to the written policies required throughout this chapter. The license holder is also responsible for ensuring that the policies comply with the statute and the applicable provisions of this chapter and are administered to provide safe, professional, quality health care.

(b) Criminal conviction. The persons described in §97.11(g) must not have been convicted of an offense described in Chapter 99, during the time frames described in that chapter.

(c) Documentation. The license holder must ensure that all documents submitted to DADS or maintained by the agency pursuant to this chapter are accurate and do not misrepresent or conceal a material fact.

(d) Compliance with enforcement orders. The license holder must comply with an order of the DADS commissioner or other enforcement orders that may be imposed on the agency in accordance with the statute and this chapter.

§97.242 ~ ORGANIZATIONAL STRUCTURE AND LINES OF AUTHORITY
(a) An agency must prepare and maintain a current written description of the agency's organizational structure. The document may be either in the form of a chart or a narrative.

(b) The description must include:
   (1) all services provided by the agency;
   (2) the governing body, the administrator, the supervising nurse, advisory committee, interdisciplinary team, and staff, as appropriate, based on services provided by the agency; and
   (3) the lines of authority and the delegation of responsibility down to and including the client care level.

§97.243 ~ ADMINISTRATIVE AND SUPERVISORY RESPONSIBILITIES
(a) Administrative responsibilities.
   (1) A license holder or the license holder's designee must designate an individual who meets the qualifications and conditions set out in §97.244 to serve as the administrator of the agency.
   (2) A license holder or the license holder's designee must designate in writing an alternate administrator who meets the qualifications and conditions of an administrator to act in the absence of the administrator.
(b) Administrator responsibilities.

(1) An administrator must be responsible for implementing and supervising the administrative policies and operations of the agency and for administratively supervising the provision of all services to agency clients on a day-to-day basis. An administrator must:

(A) manage the daily operations of the agency;
(B) organize and direct the agency's ongoing functions;
(C) administratively supervise the provision of quality care to agency clients;
(D) supervise to ensure implementation of agency policy and procedures;
(E) ensure that the documentation of services provided is accurate and timely;
(F) employ or contract with qualified personnel;
(G) ensure adequate staff education and evaluations according to requirements in §97.245(b);
(H) ensure the accuracy of public information materials and activities;
(I) implement an effective budgeting and accounting system that promotes the health and safety of the agency's clients; and
(J) supervise and evaluate client satisfaction survey reports on all clients served.

(2) An administrator or alternate administrator must be available to agency personnel in person or by telephone during the agency's operating hours and in accordance with the rules in this chapter, including §97.210, §97.404(h)(2), §97.523, and §97.527.

(3) An administrator must designate in writing an agency employee who must provide DADS surveyors entry to the agency in accordance with §97.523(e) if the administrator and alternate administrator are not available.

c) Supervision of services.

(1) Except as provided in paragraph (3) of this subsection, an agency licensed to provide LHHS, LCHHS, or hospice services must directly employ or contract with an individual who meets the qualifications in §97.244 to serve as the supervising nurse.

(2) An agency must designate in writing a similarly qualified alternate to serve as supervising nurse in the absence of the supervising nurse.

(A) The supervising nurse or alternate supervising nurse must:

(i) be available to agency personnel at all times in person or by telephone;
(ii) participate in activities relevant to services furnished, including the development of qualifications and assignment of agency personnel;
(iii) ensure that a client's plan of care or care plan is executed as written; and
(iv) ensure that an appropriate health care professional performs a reassessment of a client's needs:

(I) when there is a significant health status change in the client's condition;
(II) at the physician's request; or
(III) after hospital discharge.

(B) A supervising nurse may also be the administrator of the agency if the supervising nurse meets the qualifications and conditions of an administrator described in §97.244(a) and (b).

(3) An agency that provides only physical, occupational, speech or respiratory therapy, medical social services, or nutritional counseling is not required to employ or contract with a supervising nurse. A qualified licensed professional must supervise these services, as applicable.

d) Supervision of branch offices and alternate delivery sites. An agency must adopt and enforce a written policy relating to the supervision of branch offices or alternate delivery sites, if established. This policy must be consistent with the following:

(1) for a branch office, §97.27 and §97.321; or
(2) for an alternate delivery site, §97.29 and §97.322.
§97.244 ~ ADMINISTRATOR QUALIFICATIONS AND CONDITIONS AND SUPERVISING NURSE QUALIFICATIONS
(a) Administrator qualifications.
   (1) For an agency licensed to provide LHHS, LCHHS, or hospice services, the administrator and the alternate administrator must:
      (A) be a licensed physician, registered nurse, licensed social worker, licensed therapist, or licensed nursing home administrator with at least one year of management or supervisory experience in a health-related setting, such as:
         (i) a home and community support services agency;
         (ii) a hospital;
         (iii) a nursing facility;
         (iv) a hospice;
         (v) an outpatient rehabilitation center;
         (vi) a psychiatric facility;
         (vii) an intermediate care facility for persons with mental retardation or related conditions; or
         (viii) a licensed health care delivery setting providing services for individuals with functional disabilities; or
      (B) have a high school diploma or a general equivalency degree (GED) with at least two years of management or supervisory experience in a health-related setting, such as:
         (i) a home and community support services agency;
         (ii) a hospital;
         (iii) a nursing facility;
         (iv) a hospice;
         (v) an outpatient rehabilitation center;
         (vi) a psychiatric facility;
         (vii) an intermediate care facility for persons with mental retardation or related conditions; or
         (viii) a licensed health care delivery setting providing services for individuals with functional disabilities.
   (2) For an agency licensed to provide only PAS, the administrator and the alternate administrator must meet at least one of the following qualifications:
      (A) have a high school diploma or a GED with at least one year experience or training in caring for individuals with functional disabilities;
      (B) have completed two years of full-time study at an accredited college or university in a health-related field; or
      (C) meet the qualifications listed in paragraph (1)(A) or (B) of this subsection.
(b) Administrator conditions.
   (1) An administrator and alternate administrator must be able to read, write, and comprehend English.
   (2) An administrator and alternate administrator designated as an administrator or alternate administrator for the first time on or after December 1, 2006, must meet the initial educational training requirements specified in §97.259.
   (3) An administrator and alternate administrator designated as an administrator or alternate administrator before December 1, 2006, must meet the continuing education requirements specified in §97.260.
   (4) A person is not eligible to be the administrator or alternate administrator of any agency if the person was the administrator of an agency cited with a violation that resulted in DADS taking enforcement action against the agency while the person was the administrator of the cited agency.
      (A) This paragraph applies for 12 months after the date of the enforcement action.
(B) For purposes of this paragraph, enforcement action means license revocation, suspension, emergency suspension of a license, denial of an application for a license, or the imposition of an injunction but does not include administrative or civil penalties.

(C) If DADS prevails in one enforcement action against the agency and also proceeds with, but does not prevail in, another enforcement action based on some or all of the same violations, this paragraph does not apply.

(5) An administrator and alternate administrator must not be convicted of an offense described in Chapter 99 during the time frames described in that chapter.

(c) Supervising nurse qualifications.

(1) For an agency without a home dialysis designation, a supervising nurse and alternate supervising nurse must each:

(A) be a registered nurse (RN) licensed in Texas or in accordance with the BON rules for Nurse Licensure Compact (NLC); and

(B) have at least one year experience as an RN within the last 36 months.

(2) For an agency with home dialysis designation, a supervising nurse and alternate supervising nurse must each:

(A) be an RN licensed in Texas or in accordance with the BON rules for NLC, and:

(i) have at least three years current experience in hemodialysis; or

(ii) have at least two years experience as an RN and hold a current certification from a nationally recognized board in nephrology nursing or hemodialysis; or

(B) be a nephrologist or physician with training or demonstrated experience in the care of ESRD clients.

§97.245 ~ STAFFING POLICIES

(a) An agency must adopt and enforce written staffing policies that govern all personnel used by the agency, including employees, volunteers, and contractors.

(b) An agency's written staffing policies must:

(1) include requirements for orientation to the policies, procedures, and objectives of the agency;

(2) include requirements for participation by all personnel in job-specific training. Agency training program policies must:

(A) ensure personnel are properly oriented to tasks performed;

(B) ensure demonstration of competency for tasks when competency cannot be determined through education, license, certification, or experience;

(C) ensure a continuing systematic program for the training of all personnel; and

(D) ensure personnel are informed of changes in techniques, philosophies, goals, client's rights, and products relating to client's care;

(3) address participation by all personnel in appropriate employee development programs;

(4) include a written job description (statement of those functions and responsibilities which constitute job requirements) and job qualifications (specific education and training necessary to perform the job) for each position within the agency;

(5) include procedures for processing criminal history checks and searches of the Nurse Aide Registry (NAR) and the Employee Misconduct Registry (EMR) for unlicensed personnel in accordance with §97.247;

(6) ensure annual evaluation of employee and volunteer performance;

(7) address employee and volunteer disciplinary action and procedures;

(8) if volunteers are used by the agency, address the use of volunteers. The policy must be in compliance with §97.248;

(9) address requirements for providing and supervising services to pediatric clients. Services provided to pediatric clients must be provided by staff who have been instructed and have demonstrated competency in the care of pediatric clients; and
include a requirement that all personnel who are direct care staff and who have direct contact with clients (employed by or under contract with the agency) sign a statement that they have read, understand, and will comply with all applicable agency policies.

§97.246 ~ PERSONNEL RECORDS
(a) An agency must maintain a personnel record for an employee and volunteer. A personnel record may be maintained electronically if it meets the same requirements as a paper record. All information must be kept current. A personnel record must include the following:

1. a signed job description and qualifications for each position accepted or a signed statement that the person read the job description and qualifications for each position accepted;
2. an application for employment or volunteer agreement;
3. verification of license, permits, references, job experience, and educational requirements as conducted by the agency to verify qualifications for each position accepted;
4. performance evaluations and disciplinary actions;
5. the signed statement about compliance with agency policies required by §97.245(b)(10), if applicable; and
6. for an unlicensed employee and unlicensed volunteer whose duties would or do include face-to-face contact with a client:
   A. a printed copy of the results of the initial and annual searches of the NAR and EMR obtained from the DADS website; and
   B. documentation that the employee, in accordance with §97.247(a)(4), or volunteer, in accordance with §97.247(b)(4), received written information about the EMR.

(b) An agency may keep a complete and accurate personnel record for an employee and volunteer in any location as determined by the agency. An agency must provide personnel records not stored at the site of a survey upon request by a DADS surveyor as specified in §97.507(c).

§97.247 ~ VERIFICATION OF EMPLOYABILITY AND USE OF UNLICENSED PERSONS
(a) The provisions in this subsection apply to an unlicensed applicant for employment and an unlicensed employee, if the person's duties would or do include face-to-face contact with a client.

1. An agency must conduct a criminal history check authorized by, and in compliance with, HSC Chapter 250 for an unlicensed applicant for employment and an unlicensed employee.
2. The agency must not employ an unlicensed applicant whose criminal history check includes a conviction listed in HSC §250.006 that bars employment or a conviction the agency has determined is a contraindication to employment. If an applicant's or employee's criminal history check includes a conviction of an offense that is not listed in HSC §250.006, the agency must document its review of the conviction and its determination of whether the conviction is a contraindication to employment.

3. Before the agency hires an unlicensed applicant, or before an unlicensed employee's first face-to-face contact with a client, the agency must search the NAR and the EMR using the DADS website to determine if the applicant or employee is listed in either registry as unemployable. The agency must not employ an unlicensed applicant who is listed as unemployable in either registry.

4. The agency must provide written information about the EMR to an unlicensed employee in compliance with the requirements of §93.3(c).

5. In addition to the initial verification of employability, the agency must search the NAR and the EMR to determine if the employee is listed as unemployable in either registry as follows:
   A. for an employee most recently hired before September 1, 2009, by August 31, 2011, and at least every twelve months thereafter; and
   B. for an employee most recently hired on or after September 1, 2009, at least every 12 months.

6. The agency must immediately discharge an unlicensed employee whose duties would or do include face-to-face contact with a client when the agency becomes aware:
   A. that the employee is designated in the NAR or the EMR as unemployable; or
(B) that the employee's criminal history check reveals conviction of a crime that bars employment or that the agency has determined is a contraindication to employment.
(b) The provisions in this subsection apply to an unlicensed volunteer if the person's duties would or do include face-to-face contact with a client.
(1) An agency must conduct a criminal history check before an unlicensed volunteer's first face-to-face contact with a client.
(2) The agency must not use the services of an unlicensed volunteer for duties that would or do include face-to-face contact with a client whose criminal history information includes a conviction that bars employment under HSC §250.006 or a conviction the agency has determined is a contraindication to employment. If an unlicensed volunteer's criminal history check includes a conviction of an offense that is not listed in HSC §250.006, the agency must document its review of the conviction and its determination of whether the conviction is a contraindication to employment.
(3) Before an unlicensed volunteer's first face-to-face contact with a client, the agency must conduct a search of the NAR and the EMR using the DADS website to determine if an unlicensed volunteer is listed in either registry as unemployable. The agency must not use the services of an unlicensed volunteer who is listed as unemployable in either registry.
(4) The agency must provide written information about the EMR that complies with the requirements of §93.3(c) to an unlicensed volunteer within five working days from the date of the person's first face-to-face contact with a client.
(5) In addition to the initial verification of employability, the agency must search the NAR and the EMR to determine if a volunteer is designated in either registry as unemployable, as follows:
   (A) for a volunteer with face-to-face contact with a client for the first time before September 1, 2009, by August 31, 2011, and at least every twelve months thereafter; and
   (B) for a volunteer with face-to-face contact with a client for the first time on or after September 1, 2009, at least every twelve months.
(6) The agency must immediately stop using the services of an unlicensed volunteer for duties that would or do include face-to-face contact with a client when the agency becomes aware:
   (A) that the unlicensed volunteer is designated in the NAR or the EMR as unemployable; or
   (B) that the unlicensed volunteer's criminal history check reveals conviction of a crime that bars employment or that the agency has determined is a contraindication to employment.
(c) Upon request by DADS, an agency must provide documentation to demonstrate compliance with subsections (a) and (b) of this section.
(d) An agency that contracts with another agency or organization for an unlicensed person to provide home health services, hospice services, or personal assistance services under arrangement must also comply with the requirements in §97.289(c) - (d).

§97.248 ~ VolunTEERS
(a) This section applies to all licensed agencies. However, agencies licensed and certified to provide hospice services also must comply with 42 CFR §418.70.
(b) If an agency uses volunteers, the agency must use volunteers in defined roles under the supervision of a designated agency employee.
(1) A volunteer must meet the same requirements and standards in this chapter that apply to agency employees doing the same activities, unless the volunteer is exempt under this chapter from certain requirements or standards.
(2) Volunteers may be used in administrative and direct client care roles.
(3) The agency must document the level of volunteer activity.
(4) The agency must record expansion of care and services achieved through the use of volunteers, including type of services and the time worked.
§97.249 ~ SELF-REPORTED INCIDENTS OF ABUSE, NEGLECT, AND EXPLOITATION
(a) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise.
   (1) Abuse, neglect, and exploitation of a client 18 years of age and older have the meanings assigned by the Human Resources Code (HRC) §48.002.
   (2) Abuse, neglect, and exploitation of a child have the meanings assigned by the Family Code §261.401.
   (3) Employee means an individual directly employed by an agency, a contractor, or a volunteer.
   (4) Cause to believe means that an agency knows, suspects, or receives an allegation regarding abuse, neglect, or exploitation.
(b) An agency must adopt and enforce a written policy relating to the agency’s procedures for reporting alleged acts of abuse, neglect, and exploitation of a client by an employee of the agency.
(c) If an agency has cause to believe that a client served by the agency has been abused, neglected, or exploited by an agency employee, the agency must report the information immediately, meaning within 24 hours, to:
   (1) the Department of Family and Protective Services (DFPS) at 1-800-252-5400, or through the DFPS secure website at www.txabusehotline.org; and
   (2) DADS at 1-800-458-9858.

§97.250 ~ AGENCY INVESTIGATIONS
(a) Written policy.
   (1) An agency must adopt and enforce a written policy relating to the agency’s procedures for investigating complaints and reports of abuse, neglect, and exploitation.
   (2) The policy must meet the requirements of this section.
(b) Reports of abuse, neglect, and exploitation.
   (1) Immediately upon witnessing the act or upon receipt of the allegation, an agency must initiate an investigation of known and alleged acts of abuse, neglect, and exploitation by agency employees, including volunteers and contractors.
   (2) An agency must complete DADS Provider Investigation Report form and include the following information:
      (A) incident date;
      (B) the alleged victim;
      (C) the alleged perpetrator;
      (D) any witnesses;
      (E) the allegation;
      (F) any injury or adverse affect;
      (G) any assessments made;
      (H) any treatment required;
      (I) the investigation summary; and
      (J) any action taken.
   (3) An agency must send the completed DADS Provider Investigation Report form to DADS Complaint Intake Unit no later than the 10th day after reporting the act to the Department of Family and Protective Services and DADS.
(c) Agency complaint investigations.
   (1) An agency must investigate complaints made by a client, a client’s family or guardian, or a client’s health care provider, in accordance with this subsection, regarding:
      (A) treatment or care that was furnished by the agency;
      (B) treatment or care that the agency failed to furnish; or
      (C) a lack of respect for the client’s property by anyone furnishing services on behalf of the agency.
(2) An agency must:
   (A) document receipt of the complaint and initiate a complaint investigation within 10 days after
       the agency's receipt of the complaint; and
   (B) document all components of the investigation.

(d) Completing agency investigations. An agency must complete the investigation and documentation
    within 30 days after the agency receives a complaint or report of abuse, neglect, and exploitation,
    unless the agency has and documents reasonable cause for a delay.

(e) Retaliation.
    (1) An agency may not retaliate against a person for filing a complaint, presenting a grievance, or
        providing, in good faith, information relating to home health, hospice, or personal assistance
        services provided by the agency.
    (2) An agency is not prohibited from terminating an employee for a reason other than retaliation.

§97.251 ~ Peer Review
An agency must adopt and enforce a written policy to ensure that all professional disciplines comply with
their respective professional practice acts or title acts relating to reporting and peer review.

§97.252 ~ Financial Solvency and Business Records
An agency must have the financial ability to carry out its functions.
   (1) An agency must not intentionally or knowingly pay employees or contracted staff with checks from
       accounts with insufficient funds.
   (2) An agency must have sufficient funds to meet its payroll.
   (3) An agency must make available to DADS upon request business records relating to its ability to
       carry out its functions. If there is a question relating to the accuracy of the records or the agency's
       financial ability to carry out its functions, DADS or its designee may conduct a more extensive
       review of the records.
   (4) An agency must maintain business records in their original state. Each entry must be accurate and
       dated with the date of entry. Correction fluid or tape may not be used in the record. Corrections
       must be made in accordance with standard accounting practices.

§97.253 ~ Disclosure of Drug Testing Policy
(a) An agency must have a written policy describing whether it will conduct drug testing of its employees
    who have direct contact with clients.
(b) If an agency conducts drug testing, the written policy must describe the method by which drug testing
    is conducted.
(c) If an agency does not practice drug testing of its employees, the written policy must state that the
    agency does not conduct drug testing of its employees.
(d) An agency must provide a copy of the policy to anyone applying for services from the agency and
    any person who requests it.

§97.254 ~ Billing and Insurance Claims
The agency must adopt and enforce a written policy to ensure that the agency submits accurate billings
and insurance claims.

§97.255 ~ Prohibition of Solicitation of Patients
(a) An agency must adopt and enforce a written policy to ensure compliance of the agency and its
    employees and contractors with the Occupations Code, Chapter 102. For the purpose of this section
    a patient is considered to be a client.
(b) DADS may take enforcement action against an agency in accordance with §97.601 and §97.602, if
    the agency violates Occupations Code, §102.001 or §102.006.
§97.256 ~ EMERGENCY PREPAREDNESS PLANNING AND IMPLEMENTATION

(a) An agency must have a written emergency preparedness and response plan that comprehensively describes its approach to a disaster that could affect the need for its services or its ability to provide those services. The written plan must be based on a risk assessment that identifies the disasters from natural and man-made causes that are likely to occur in the agency’s service area. With the exception of a freestanding hospice inpatient unit, DADS does not require an agency to physically evacuate or transport a client.

(b) Agency personnel that must be involved with developing, maintaining, and implementing an agency's emergency preparedness and response plan include:
   (1) the administrator;
   (2) the supervising nurse, if the agency is required to employ or contract with a supervising nurse as required by §97.243;
   (3) the agency disaster coordinator; and
   (4) the alternate disaster coordinator.

(c) An agency’s written emergency preparedness and response plan must:
   (1) designate, by title, an employee, and at least one alternate employee to act as the agency's disaster coordinator;
   (2) include a continuity of operations business plan that addresses emergency financial needs, essential functions for client services, critical personnel, and how to return to normal operations as quickly as possible;
   (3) include how the agency will monitor disaster-related news and information, including after hours, weekends, and holidays, to receive warnings of imminent and occurring disasters;
   (4) include procedures to release client information in the event of a disaster, in accordance with the agency’s written policy required by §97.301(a)(2); and
   (5) describe the actions and responsibilities of agency staff in each phase of emergency planning, including mitigation, preparedness, response, and recovery.

(d) The response and recovery phases of the plan must describe:
   (1) the actions and responsibilities of agency staff when warning of an emergency is not provided;
   (2) who at the agency will initiate each phase;
   (3) a primary mode of communication and alternate communication or alert systems in the event of telephone or power failure; and
   (4) procedures for communicating with:
      (A) staff;
      (B) clients or persons responsible for a client's emergency response plan;
      (C) local, state, and federal emergency management agencies; and
      (D) other entities including DADS and other healthcare providers and suppliers.

(e) An agency’s emergency preparedness and response plan must include procedures to triage clients that allow the agency to:
   (1) readily access recorded information about an active client's triage category in the event of an emergency to implement the agency's response and recovery phases, as described in subsection (d) of this section; and
   (2) categorize clients into groups based on:
      (A) the services the agency provides to a client;
      (B) the client's need for continuity of the services the agency provides; and
      (C) the availability of someone to assume responsibility for a client's emergency response plan if needed by the client.

(f) The agency's emergency preparedness and response plan must include procedures to identify a client who may need evacuation assistance from local or state jurisdictions because the client:
   (1) cannot provide or arrange for his or her transportation; or
   (2) has special health care needs requiring special transportation assistance.
(g) If the agency identifies a client who may need evacuation assistance, as described in subsection (f) of this section, agency personnel must provide the client with the amount of assistance the client requests to complete the registration process for evacuation assistance if the client:
   (1) wants to register with the Transportation Assistance Registry, accessed by dialing 2-1-1; and
   (2) is not already registered, as reported by the client or legally authorized representative.

(h) An agency must provide and discuss the following information about emergency preparedness with each client:
   (1) the actions and responsibilities of agency staff during and immediately following an emergency;
   (2) the client's responsibilities in the agency's emergency preparedness and response plan;
   (3) materials that describe survival tips and plans for evacuation and sheltering in place; and
   (4) a list of community disaster resources that may assist a client during a disaster, including the Transportation Assistance Registry available through 2-1-1 Texas, and other community disaster resources provided by local, state, and federal emergency management agencies. An agency's list of community disaster resources must include information on how to contact the resources directly or instructions to call 2-1-1 for more information about community disaster resources.

(i) An agency must orient and train employees, volunteers, and contractors about their responsibilities in the agency's emergency preparedness and response plan.

(j) An agency must complete an internal review of the plan at least annually, and after each actual emergency response, to evaluate its effectiveness and to update the plan as needed.

(k) As part of the annual internal review, an agency must test the response phase of its emergency preparedness and response plan in a planned drill if not tested during an actual emergency response. Except for a freestanding hospice inpatient unit, a planned drill can be limited to the agency's procedures for communicating with staff.

(l) An agency must make a good faith effort to comply with the requirements of this section during a disaster. If the agency is unable to comply with any of the requirements of this section, it must document in the agency's records attempts of staff to follow procedures outlined in the agency's emergency preparedness and response plan.

(m) An agency is not required to continue to provide care to clients in emergency situations that are beyond the agency's control and that make it impossible to provide services, such as when roads are impassable or when a client relocates to a place unknown to the agency. An agency may establish links to local emergency operations centers to determine a mechanism by which to approach specific areas within a disaster area in order for the agency to reach its clients.

(n) If written records are damaged during a disaster, the agency must not reproduce or recreate client records except from existing electronic records. Records reproduced from existing electronic records must include:
   (1) the date the record was reproduced;
   (2) the agency staff member who reproduced the record; and
   (3) how the original record was damaged.

(o) Notwithstanding the provisions specified in Division 2, no later than five working days after an agency temporarily relocates a place of business, or temporarily expands its service area resulting from the effects of an emergency or disaster, an agency must notify and provide the following information to the DADS HCSSA Licensing Unit:
   (1) if temporarily relocating a place of business:
      (A) the license number for the place of business and the date of relocation;
      (B) the physical address and phone number of the location; and
      (C) the date the agency returns to a place of business after the relocation; or
   (2) if temporarily expanding the service area to provide services during a disaster:
      (A) the license number and revised boundaries of the service area;
      (B) the date the expansion begins; and
      (C) the date the expansion ends.
(p) An agency must provide the notice and information described in subsection (o) of this section by fax or email. If fax and email are unavailable, the agency may notify the DADS licensing unit by telephone, but must provide the notice and information in writing as soon as possible. If communication with the DADS licensing unit is not possible, the agency must provide the notice and information by fax, e-mail, or telephone to the designated survey office.

§97.257 ~ MEDICARE CERTIFICATION OPTIONAL
(a) An agency that applies for the category of LCHHS must comply with the regulations in the Medicare Conditions of Participation for Home Health Agencies, 42 CFR Part 484, pending approval of certification granted by CMS. An agency providing hospice services and applying for participation in the Medicare program must comply with the Medicare Conditions of Participation for Hospice Services, 42 CFR Part 418.
(b) Upon DADS’ receipt of written approval from CMS, DADS will amend the licensing status of the agency to include the LCHHS category. The agency must then comply with §97.402.

§97.259 ~ INITIAL EDUCATIONAL TRAINING IN ADMINISTRATION OF AGENCIES
(a) This section applies only to an administrator and alternate administrator designated as an administrator or alternate administrator for the first time on or after December 1, 2006.
(b) In addition to the qualifications and conditions described in §97.244, a first-time administrator and alternate administrator of an agency must each complete a total of 24 clock hours of educational training in the administration of an agency before the end of the first 12 months after designation to the position.
(c) Prior to designation, a first-time administrator or alternate administrator must complete eight clock hours of educational training in the administration of an agency. The initial eight clock hours must be completed during the 12 months immediately preceding the date of designation to the position. The initial eight clock hours must include:
   (1) information on the licensing standards for an agency; and
   (2) information on the state and federal laws applicable to an agency, including:
      (A) HSC Chapter 142, Home and Community Support Services, and HSC Chapter 250, Nurse Aide Registry and Criminal History Checks of Employees and Applicants for Employment in Certain Facilities Serving the Elderly or Persons with Disabilities;
      (B) HRC Chapter 102, Rights of the Elderly;
      (C) the Americans with Disabilities Act;
      (D) the Civil Rights Act of 1991;
      (E) the Rehabilitation Act of 1993;
      (F) the Family and Medical Leave Act of 1993; and
      (G) the Occupational Safety and Health Administration (OSHA) requirements.
(d) A first-time administrator and alternate administrator must complete an additional 16 clock hours of educational training before the end of the first 12 months after designation to the position. Any of the additional 16 clock hours may be completed prior to designation if completed during the 12 months immediately preceding the date of designation to the position. The additional 16 clock hours must include the following subjects and may include other topics related to the duties of an administrator:
   (1) information regarding fraud and abuse detection and prevention;
   (2) legal issues regarding advance directives;
   (3) client rights, including the right to confidentiality;
   (4) agency responsibilities;
   (5) complaint investigation and resolution;
   (6) emergency preparedness planning and implementation;
   (7) abuse, neglect, and exploitation;
   (8) infection control;
   (9) nutrition (for agencies licensed to provide inpatient hospice services); and
(10) the Outcome and Assessment Information Set (OASIS) (for agencies licensed to provide licensed and certified home health services).

(e) The 24-hour educational training requirement described in subsection (b) of this section must be met through structured, formalized classes, correspondence courses, competency-based computer courses, training videos, distance learning programs, or off-site training courses. Subject matter that deals with the internal affairs of an organization does not qualify for credit.

(1) The training must be provided or produced by:
(A) an academic institution;
(B) a recognized state or national organization or association;
(C) an independent contractor who consults with agencies; or
(D) an agency.

(2) If an agency or independent contractor provides or produces the training, the training must be approved by DADS or recognized by a state or national organization or association. The agency must maintain documentation of this approval or recognition for review by DADS surveyors.

(3) A first-time administrator and alternate administrator may apply joint training provided by DADS toward the 24 hours of educational training required by this section if the joint training meets the educational training requirements described in subsections (c) and (d) of this section.

(f) Documentation of administrator and alternate administrator training must:
(1) be on file at the agency; and
(2) contain the name of the class or workshop, the course content (such as the curriculum), the hours and dates of the training, and the name and contact information of the entity and trainer who provided the training.

(g) A first-time administrator and alternate administrator must not apply a pre-survey conference toward the 24 hours of educational training required in this section.

(h) After completing the 24 hours of initial educational training prior to or during the first 12 months after designation as a first-time administrator and alternate administrator, an administrator and alternate administrator must then complete the continuing education requirements as specified in §97.260 in each subsequent 12-month period after designation.

§97.260 ~ CONTINUING EDUCATION IN ADMINISTRATION OF AGENCIES
(a) In addition to the qualifications and conditions described in §97.244, an administrator and alternate administrator must complete 12 clock hours of continuing education within each 12-month period beginning with the date of designation. The 12 clock hours of continuing education must include at least two of the following topics and may include other topics related to the duties of an administrator:
(1) any one of the educational training subjects listed in §97.259(d);
(2) development and interpretation of agency policies;
(3) basic principles of management in a licensed health-related setting;
(4) ethics;
(5) quality improvement;
(6) risk assessment and management;
(7) financial management;
(8) skills for working with clients, families, and other professional service providers;
(9) community resources; or
(10) marketing.

(b) This subsection applies only to an agency administrator or alternate administrator designated as an agency administrator or alternate administrator before December 1, 2006, who has not served as an administrator or alternate administrator for 180 days or more immediately preceding the date of designation. Within the first 12 months after the date of designation, at least eight of the 12 clock hours of continuing education must include the topics listed in §97.259(c). The remaining four hours of continuing education must include topics related to the duties of an administrator and may include the topics listed in subsection (a) of this section.
(c) Documentation of administrator and alternate administrator continuing education must:
   (1) be on file at the agency; and
   (2) contain the name of the class or workshop, the topics covered, and the hours and dates of the
       training.
(d) An administrator or alternate administrator must not apply the pre-survey conference toward the
continuing education requirements in this section.

DIVISION 4
§97.281 ~ CLIENT CARE POLICIES
An agency must adopt and enforce a written policy that specifies the agency's client care practices. The
written policy must include the following elements if covered under the scope of services provided by the
agency:
   (1) initial assessment, reassessment;
   (2) start of care, transfer, and discharge;
   (3) intravenous services;
   (4) care of the pediatric client;
   (5) triaging clients in the event of disaster;
   (6) how to handle emergencies in the home;
   (7) safety of staff;
   (8) procedures the staff will perform for clients, such as dressing changes, Foley catheter changes,
       wound irrigation, administration of medication;
   (9) psychiatric nursing procedures;
   (10) patient and caregiver teaching relating to disease process/procedures;
   (11) care planning;
   (12) care of the dying patient/client;
   (13) receiving physician orders;
   (14) performing waived testing;
   (15) medication monitoring; and
   (16) anything else pertaining to client care.

§97.282 ~ CLIENT CONDUCT AND RESPONSIBILITY AND CLIENT RIGHTS
(a) An agency must adopt and enforce a written policy governing client conduct and responsibility and
client rights in accordance with this section. The written policy must include a grievance mechanism
under which a client can participate without fear of reprisal.
(b) An agency must protect and promote the rights of all clients.
(c) An agency must comply with the provisions of the HRC Chapter 102, Rights of the Elderly, which
applies to a client 60 years of age or older.
(d) At the time of admission, an agency must provide a client who receives licensed home health
services, licensed and certified home health services, hospice services, or personal assistance
services with a written statement that informs the client that a complaint against the agency may be
directed to DADS Consumer Rights and Services Division, P.O. Box 149030, Austin, Texas 78714-
9030, toll free 1-800-458-9858. The statement also may inform the client that a complaint against the
agency may be directed to the administrator of the agency. The statement about complaints directed
to the administrator also must include the time frame in which the agency will review and resolve the
complaint.
(e) In advance of furnishing care to a client or during the initial evaluation visit before the initiation of
treatment, an agency must provide the client or their legal representative with a written notice of all
policies governing client conduct and responsibility and client rights.
(f) A client has the following rights:
   (1) A client has the right to be informed in advance about the care to be furnished, the plan of care,
       expected outcomes, barriers to treatment, and any changes in the care to be furnished. The
       agency must ensure that written informed consent specifying the type of care and services that
may be provided by the agency has been obtained for every client, either from the client or their legal representative. The client or the legal representative must sign or mark the consent form.

(2) A client has the right to participate in planning the care or treatment and in planning a change in the care or treatment.
   (A) An agency must advise or consult with the client or legal representative in advance of any change in the care or treatment.
   (B) A client has the right to refuse care and services.
   (C) A client has the right to be informed, before care is initiated, of the extent to which payment may be expected from the client, a third-party payer, and any other source of funding known to the agency.

(3) A client has the right to have assistance in understanding and exercising the client's rights. The agency must maintain documentation showing that it has complied with the requirements of this paragraph and that the client demonstrates understanding of the client's rights.

(4) A client has the right to exercise rights as a client of the agency.

(5) A client has the right to have the client's person and property treated with consideration, respect, and full recognition of the client's individuality and personal needs.

(6) A client has the right to be free from abuse, neglect, and exploitation by an agency employee, volunteer, or contractor.

(7) A client has the right to confidential treatment of the client's personal and medical records.

(8) A client has the right to voice grievances regarding treatment or care that is or fails to be furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the agency and must not be subjected to discrimination or reprisal for doing so.

(g) In the case of a client adjudged incompetent, the rights of the client are exercised by the person appointed by law to act on the client's behalf.

(h) In the case of a client who has not been adjudged incompetent, any legal representative may exercise the client's rights to the extent permitted by law.

§97.283 ~ ADVANCE DIRECTIVES

(a) An agency must maintain a written policy regarding implementation of advance directives. The policy must be in compliance with HSC Chapter 166, Advance Directives Act. The policy must include a clear and precise statement of any procedure the agency is unwilling or unable to provide or withhold in accordance with an advance directive.

(b) The agency must provide written notice to a client of the written policy required by subsection (a) of this section. The notice must be provided at the earlier of:
   (1) the time the client is admitted to receive services from the agency; or
   (2) the time the agency begins providing care to the client.

(c) If, at the time notice must be provided under subsection (b) of this section, the client is incompetent or otherwise incapacitated and unable to receive the notice, the agency must provide the required written notice, in the following order of preference, to:
   (1) the client's legal guardian;
   (2) a person responsible for the health care decisions of the client;
   (3) the client's spouse;
   (4) the client's adult child;
   (5) the client's parent; or
   (6) the person admitting the client.

(d) If subsection (c) of this section applies, except as provided by subsection (e) of this section, if an agency is unable, after a diligent search, to locate an individual listed by subsection (c) of this section, the agency is not required to provide the notice.

(e) If a client who was incompetent or otherwise incapacitated and unable to receive the notice required by this subsection at the time notice was to be provided under subsection (b) of this section later becomes able to receive the notice, the agency must provide the written notice at the time the client becomes able to receive the notice.
(f) DADS assesses an administrative penalty of $500 without an opportunity to correct against an agency that violates this section.

§97.284 ~ LABORATORY SERVICES
An agency that provides laboratory services must adopt and enforce a written policy to ensure that the agency meets the Clinical Laboratory Improvement Act, 42 United States Code (USC) Annotated, §263a, (CLIA 1988). CLIA 1988 applies to all agencies with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

§97.285 ~ INFECTION CONTROL
An agency must adopt and enforce written policies addressing infection control, including the prevention of the spread of infectious and communicable disease. The policies must:

(1) ensure compliance by the agency, its employees, and its contractors with:
   (A) the Communicable Disease Prevention and Control Act, HSC Chapter 81;
   (B) the Occupational Safety and Health Administration (OSHA), 29 CFR Part 1910.1030 and Appendix A relating to Bloodborne Pathogens; and
   (C) the Human Immunodeficiency Virus Services Act, HSC Chapter 85, Subchapter I, concerning the prevention of the transmission of human immunodeficiency virus and hepatitis B virus; and

(2) require documentation of infections that the client acquires while receiving services from the agency.
   (A) If an agency is licensed to provide services other than personal assistance services, documentation must include the date that the infection was detected, the client's name, primary diagnosis, signs and symptoms, type of infection, pathogens identified, and treatment.
   (B) If an agency is licensed to provide only personal assistance services, documentation must include the date that the infection was disclosed to the agency employee, the client's name, and treatment as disclosed by the client.

§97.286 ~ DISPOSAL OF SPECIAL OR MEDICAL WASTE
(a) An agency must adopt and enforce a written policy for the safe handling and disposal of biohazardous waste and materials, if applicable.

(b) An agency that generates special or medical waste while providing home health services must dispose of the waste according to the requirements in 25 TAC, §§1.131-1.137. An agency must provide both verbal and written instructions to the agency's clients regarding the proper procedure for disposing of sharps. For purposes of this subsection, sharps include hypodermic needles, hypodermic syringes with attached needles, scalpel blades, razor blades, disposable razors, disposable scissors used in medical procedures, and intravenous stylets and rigid introducers.

§97.287 ~ QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT
(a) Quality Assessment and Performance Improvement (QAPI) Program.
   (1) An agency must maintain a QAPI Program that is implemented by a QAPI Committee. The QAPI Program must be ongoing, focused on client outcomes that are measurable, and have a written plan of implementation. The QAPI Committee must review and update or revise the plan of implementation at least once within a calendar year, or more often if needed. The QAPI Program must include:
      (A) a system that measures significant outcomes for optimal care. The QAPI Committee must use the measures in the care planning and coordination of services and events. The measures must include the following as appropriate for the scope of services provided by the agency:
         (i) an analysis of a representative sample of services furnished to clients contained in both active and closed records;
(ii) a review of:
   (I) negative client care outcomes;
   (II) complaints and incidents of unprofessional conduct by licensed staff and misconduct by unlicensed staff;
   (III) infection control activities;
   (IV) medication administration and errors; and
   (V) effectiveness and safety of all services provided, including:
      (a) the competency of the agency's clinical staff;
      (b) the promptness of service delivery; and
      (c) the appropriateness of the agency's responses to client complaints and incidents;

(iii) a determination that services have been performed as outlined in the individualized service plan, care plan, or plan of care; and

(iv) an analysis of client complaint and satisfaction survey data; and

(B) an annual evaluation of the total operation, including services provided under contract or arrangement.
   (i) An agency must use the evaluation to correct identified problems and, if necessary, to revise policies.
   (ii) An agency must document corrective action to ensure that improvements are sustained over time.

(2) An agency must immediately correct identified problems that directly or potentially threaten the client care and safety.

(3) QAPI documents must be kept confidential and be made available to DADS staff upon request.

(b) QAPI Committee membership. At a minimum, the QAPI Committee must consist of:
   (1) the administrator;
   (2) the supervising nurse or therapist, or the supervisor of an agency licensed to provide personal assistance services; and
   (3) an individual representing the scope of services provided by the agency.

(c) Frequency of QAPI Committee meeting. The QAPI Committee must meet twice a year or more often if needed.

§97.288 ~ COORDINATION OF SERVICES
(a) An agency must adopt and enforce a written policy that requires effective coordination of care with all service providers involved in the care of a client, including physicians, contracted health care professionals, and other agencies.

(b) The agency must document the steps taken to meet subsection (a) of this section in the client record.

§97.289 ~ INDEPENDENT CONTRACTORS AND ARRANGED SERVICES
(a) Independent contractors. If an agency uses independent contractors, there must be a contract between each independent contractor that performs services and the agency. The contract must be enforced by the agency and clearly designate:
   (1) that clients are accepted for care only by the agency;
   (2) the services to be provided by the contractor and how they will be provided;
   (3) the necessity of the contractor to conform to all applicable agency policies, including personnel qualifications;
   (4) the contractor’s responsibility for participating in developing the plan of care, care plan or individualized service plan;
   (5) the manner in which services will be coordinated and evaluated by the agency in accordance with §97.288;
(6) the procedures for:
   (A) submitting information and documentation by the contractor in accordance with the agency's 
       client record policies;
   (B) scheduling of visits by the contractor or the agency;
   (C) periodic client evaluation by the contractor; and 
   (D) determining charges and reimbursement payable by the agency for the contractor's services 
       under the contract.

(b) Arranged services. Home health services, hospice services, or personal assistance services provided 
by an agency under arrangement with another agency or organization must be provided under a 
written contract conforming to the requirements specified in subsection (a) of this section.

(c) If an agency contracts with another agency or organization for an unlicensed person to provide home 
health services, hospice services, or personal assistance services under arrangement, the agency 
must ensure that either it or the contracting agency or organization:
   (1) searches the NAR and the EMR before the unlicensed person's first face-to-face contact with a 
       client of the agency using the DADS website to confirm that the unlicensed person is not listed in 
       either registry as unemployable;
   (2) provides written information to the unlicensed person about the EMR that complies with the 
       requirements of §93.3(c); and
   (3) searches the NAR and the EMR at least every twelve months using the DADS Internet website to 
       confirm that the person is not listed in either registry as unemployable.

(d) If an agency contracts with another agency or organization for an unlicensed person to provide home 
health services, hospice services, or personal assistance services under arrangement, the agency 
must ensure that the contracting agency or organization:
   (1) conducts a criminal history check before the unlicensed person's first face-to-face contact with a 
       client of the agency; and
   (2) verifies that the unlicensed person's criminal history information does not include a conviction that 
       bars employment under the HSC §250.006.

(e) Documentation for contract staff. An agency is not required to maintain a personnel record for 
independent contractors or staff who provide services under arrangement with another agency or 
organization. Upon request by DADS, an agency must provide documentation at the site of a survey 
within eight working hours of the request to demonstrate:
   (1) that independent contractors or staff under arrangement meet the agency's written job 
       qualifications for the position and duties performed;
   (2) the agency ensures compliance with subsection (c) of this section for unlicensed staff providing 
       services to the agency's clients under arrangement; and
   (3) the agency complies with subsection (d) of this section for unlicensed staff providing services to 
       the agency's clients under arrangement by providing a written statement, signed by a person 
       authorized to make decisions on personnel matters for the contracting agency or organization, 
       attesting that a criminal history check was conducted before an unlicensed person's first face-to- 
       face contact with a client and did not include a conviction barring employment under HSC 
       §250.006.

§97.290 ~ BACKUP SERVICES AND AFTER HOURS CARE

(a) Backup services. An agency must adopt and enforce a written policy to ensure that backup services 
are available when an agency employee or contractor is not available to deliver the services.
   (1) Backup services may be provided by an agency employee, a contractor, or the client's designee 
       who is willing and able to provide the necessary services.
   (2) If the client's designee has agreed to provide backup services required by this section, the 
       agency must have the designee sign a written agreement to be the backup service provider. The 
       agency must keep the agreement in the client's file.
   (3) An agency must not coerce a client to accept backup services.
(b) After hours care. An agency must adopt and enforce a written policy to ensure that clients are educated in how to access care from the agency or another health care provider after regular business hours.

§97.291 ~ AGENCY DISSOLUTION
An agency must adopt and enforce a written policy that describes the agency's written contingency plan.

1. The plan must be implemented in the event of dissolution to assure continuity of client care.

2. The plan must:
   A. be consistent with §97.295;
   B. include procedures for:
      i. notifying the client of the agency's dissolution;
      ii. documenting the notification;
      iii. carrying out the notification; and
   C. comply with §97.217(a)(2).

§97.292 ~ AGENCY AND CLIENT AGREEMENT AND DISCLOSURE
(a) The agency must provide the client or the client's family with a written agreement for services. The agency must comply with the terms of the agreement. The agreement must include at a minimum the following:

1. notification of client rights;
2. documentation concerning notification to the client of the availability of medical power of attorney for health care, advance directive or "Do Not Resuscitate" orders in accordance with the applicable law;
3. services to be provided;
4. supervision by the agency of services provided;
5. agency charges for services rendered if the charges will be paid in full or in part by the client or the client's family, or on request;
6. a written statement containing procedures for filing a complaint in accordance with §97.282(d); and
7. a client agreement to and acknowledgement of services by home health medication aides, if home health medication aides are used.

(b) The agency must obtain an acknowledgment of receipt from the client or his family of the items listed under subsection (a) of this section. This acknowledgment of receipt must be kept in the client's record.

§97.293 ~ CLIENT LIST AND SERVICES
An agency must maintain a current list of clients for each category of service licensed.

1. The list must include all services being delivered by the agency and services being delivered under contract.

2. The client list must include the client's name, identification or clinical record number, start of care date or admission date, certification period (if applicable), diagnosis or functional assessment (as appropriate), and the disciplines that are providing services.

§97.294 ~ TIME FRAMES FOR THE INITIATION OF CARE OR SERVICES
An agency must adopt and enforce a written policy establishing time frames for the initiation of care or services.

§97.295 ~ CLIENT TRANSFER OR DISCHARGE NOTIFICATION REQUIREMENTS
(a) Except as provided in subsection (e) of this section, an agency intending to transfer or discharge a client must:

1. provide written notification to the client or the client's parent, family, spouse, significant other, or legal representative; and

2. notify the client's attending physician or practitioner if he is involved in the agency's care of the client.
(b) An agency must ensure delivery of the written notification no later than five days before the date on which the client will be transferred or discharged.

(c) The agency must deliver the required notice by hand or by mail.

(d) If the agency delivers the written notice by mail:
   (1) the notice must be mailed at least eight working days before the date of discharge or transfer; and
   (2) the agency must speak with the client by telephone or in person to ensure the client's knowledge of the transfer or discharge at least five days before the date of discharge or transfer.

(e) An agency may transfer or discharge a client without prior notice required by subsection (b) of this section:
   (1) upon the client's request;
   (2) if the client's medical needs require transfer, such as a medical emergency;
   (3) in the event of a disaster when the client's health and safety is at risk in accordance with provisions of §97.256;
   (4) for the protection of staff or a client after the agency has made a documented reasonable effort to notify the client, the client's family and physician, and appropriate state or local authorities of the agency's concerns for staff or client safety, and in accordance with agency policy;
   (5) according to physician orders; or
   (6) if the client fails to pay for services, except as prohibited by federal law.

(f) An agency must keep the following in the client's file:
   (1) a copy of the written notification provided to the client or the client's parent, family, spouse, significant other, or legal representative;
   (2) documentation of the personal contact with the client if the required notice was delivered by mail; and
   (3) documentation that the client's attending physician or practitioner was notified of the date of discharge.

§97.296 ~ PHYSICIAN DELEGATION AND PERFORMANCE OF PHYSICIAN-DELEGATED TASKS
(a) An agency must adopt and enforce a written policy that states whether or not physician delegation will be honored by the agency. If an agency accepts physician delegation, the agency must comply with the Medical Practice Act, Occupations Code, Chapter 157, concerning physician delegation.

(b) An agency may accept delegation from a physician only if the agency receives the following from the physician:
   (1) the name of the client;
   (2) the name of the delegating physician;
   (3) the tasks to be performed;
   (4) the name of the individuals to perform the tasks;
   (5) the time frame for the delegation order; and
   (6) if the task is medication administration, the medication to be given, route, dose, and frequency.

§97.297 ~ RECEIPT OF PHYSICIAN ORDERS
An agency must adopt and enforce a written policy describing protocols and procedures agency staff must follow when receiving physician orders.

(1) The policy must address the time frame for countersignature of physician verbal orders.

(2) Signed physician orders may be submitted via facsimile machine. The agency is not required to have the original signatures on file. However, the agency must be able to obtain original signatures if an issue surfaces that would require verification of an original signature. The policy must include protocols to follow when accepting physician orders via facsimile. If physician orders are accepted via facsimile, the policy must:
   (A) outline safeguards to assure that transmitted information is sent to the appropriate individual; and
   (B) outline the procedures to be followed in the case of misdirected transmission.
§97.298 ~ Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel and Tasks Not Requiring Delegation
(a) An agency must adopt and enforce a written policy to ensure compliance with the following rules adopted by the BON:
   (1) 22 TAC, Chapter 224, Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments; and
   (2) 22 TAC, Chapter 225, RN Delegation to Unlicensed Personnel and Tasks Not Requiring Delegation in Independent Living Environments for Clients with Stable and Predictable Conditions.
(b) Requirements for RN delegation for personal assistance service clients are located in §97.404.

§97.299 ~ Nursing Education, Licensure and Practice
If providing nursing services, an agency must adopt and enforce a written policy to ensure compliance with the rules of BON adopted at 22 TAC Chapters 211 - 226.

§97.300 ~ Medication Administration
(a) This section applies only to clients to whom agency staff administer medications.
(b) An agency must adopt and enforce a written policy for maintaining a current medication list and a current medication administration record.
   (1) A client's practitioner must order administration of medication.
   (2) An agency may incorporate a current medication list and medication administration record into one document.
      (A) An agency must use the medication list to identify possible ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindications.
      (B) An agency must document in the medication administration record or clinical notes any medication that is not administered and the reason it was not administered.
   (3) An individual delivering care must report any adverse reaction to a supervisor and document this in the client's record on the day of occurrence. If the adverse reaction occurs after regular business hours, the individual delivering care must report the adverse reaction as soon as it is disclosed.

§97.301 ~ Client Records
(a) In accordance with accepted principles of practice, an agency must establish and maintain a client record system to ensure that the care and services provided to each client are completely and accurately documented, readily accessible and systematically organized to facilitate the compilation and retrieval of information.
   (1) An agency must establish a record for each client and must maintain the record in accordance with and contain the information described in paragraph (9) of this subsection. An agency must keep a single file or separate files for each category of service provided to the client and the client's family. Hospice services provided to a client's family must be documented in the clinical record.
   (2) The agency must adopt and enforce written procedures regarding the use and removal of records, the release of information, and when applicable, the incorporation of clinical, progress, or other notes into the client record. An agency may not release any portion of a client record to anyone other than the client except as allowed by law.
   (3) All information regarding the client's care and services must be centralized in the client's record and be protected against loss or damage.
   (4) The agency must establish an area for original active client record storage at the agency's place of business. The original active client record must be stored at the place of business (parent agency, branch office, or alternate delivery site) from which services are actually provided. Original active client records must not be stored at an administrative support site or records storage facility.
(5) The agency must ensure that each client's record is treated with confidentiality, safeguarded against loss and unofficial use, and is maintained according to professional standards of practice.

(6) A clinical record must be an original, a microfilmed copy, an optical disc imaging system, or a certified copy.

(A) An original record is a signed paper record or an electronically signed computer record. A signed paper record may include a physician’s stamped signature if the agency meets the following requirements:
   (i) An agency must have on file at the agency a current written authorization letter from the physician whose signature the stamp represents, stating that he is the only person authorized to have the stamp and use it.
   (ii) The authorization letter must be dated before a stamped record from the physician was accepted by the agency.
   (iii) An agency must obtain a new authorization letter from the physician annually. A physician authorization letter is void one year from the date of the letter.
   (iv) The authorization letter must be manually signed by the physician and include a copy of the stamped signature that the physician will use.

(B) Computerized records must meet all requirements of paper records, including protection from unofficial use and retention for the period specified in subsection (b) of this section.

(C) An agency must ensure that entries regarding the delivery of care or services are not altered without evidence and explanation of such alteration.

(7) Each entry to the client record must be current, accurate, signed, and dated with the date of entry by the individual making the entry. The record must include all services whether furnished directly or under arrangement. Correction fluid or tape must not be used in the record. Corrections must be made by striking through the error with a single line and must include the date the correction was made and the initials of the person making the correction.

(8) Inactive client records may be preserved on microfilm, optical disc or other electronic means and may be stored at the parent agency location, branch office, alternate delivery site, administrative support site, or records storage facility. Security must be maintained and the record must be readily retrievable by the agency.

(9) Each client record must include the following elements as applicable to the scope of services provided by the agency:

(A) client application for services including, but not limited to: full name; sex; date of birth; name, address, and telephone number of parents of a minor child, or legal guardian, or others as identified by the individual; physician's name and telephone numbers, including emergency numbers; and services requested;

(B) initial health assessment, pertinent medical history, and subsequent health assessments;

(C) care plan, plan of care, or individualized service plan, as applicable. The care plan or the plan of care must include, as applicable, medication, dietary, treatment, and activities orders. The requirements for the individualized service plan for personal assistance service clients are located in §97.404. The requirements for the plan of care for hospice clients are located in §97.403;

(D) clinical and progress notes. Such notes must be written the day service is rendered and incorporated into the client record within 14 working days;

(E) current medication list;

(F) medication administration record (if medication is administered by agency staff). Notation must also be made in the medication administration record or in the clinical notes of medications not given and the reason. Any adverse reaction must be reported to a supervisor and documented in the client record;

(G) records of supervisory visits;
(H) complete documentation of all known services and significant events. Documentation must show that effective interchange, reporting, and coordination of care occurs as required in §97.288;
(I) for clients 60 years and older, acknowledgment of the client's receipt of a copy of the HRC Chapter 102, Rights of the Elderly;
(J) acknowledgment of the client's receipt of the agency's policy relating to the reporting of abuse, neglect, or exploitation of a client;
(K) documentation that the client has been informed of how to register a complaint in accordance with §97.282(d);
(L) client agreement to and acknowledgment of services by home health medication aides, if home health medication aides are used;
(M) discharge summary, including the reason for discharge or transfer and the agency's documented notice to the client, the client's physician (if applicable), and other individuals as required in §97.295;
(N) acknowledgement of receipt of the notice of advance directives;
(O) services provided to the client's family (as applicable); and
(P) consent and authorization and election forms, as applicable.

(b) An agency must adopt and enforce a written policy relating to the retention of records in accordance with this subsection.
(1) An agency must retain original client records for a minimum of five years after the discharge of the client.
(2) The agency may not destroy client records that relate to any matter that is involved in litigation if the agency knows the litigation has not been finally resolved.
(3) There must be an arrangement for the preservation of inactive records to insure compliance with this subsection.

§97.302 ~ PRONOUNCEMENT OF DEATH
An agency must adopt and enforce a written policy on pronouncement of death if that function is carried out by an agency registered nurse. The policy must be in compliance with the HSC §671.001.

§97.303 ~ STANDARDS FOR POSSESSION OF STERILE WATER OR SALINE, CERTAIN VACCINES OR TUBERCULIN, AND CERTAIN DANGEROUS DRUGS
An agency that possesses sterile water or saline, certain vaccines or tuberculin, or certain dangerous drugs as specified by this section must comply with the provisions of this section.
(1) Possession of sterile water or saline. An agency or its employees who are registered nurses or licensed vocational nurses may purchase, store, or transport for the purpose of administering to their home health or hospice clients under physician's orders:
   (A) sterile water for injection and irrigation; and
   (B) sterile saline for injection and irrigation.
(2) Possession of certain vaccines or tuberculin. 
   (A) An agency or its employees who are registered nurses or licensed vocational nurses may purchase, store, or transport for the purpose of administering to the agency's employees, home health or hospice clients, or client family members under physician's standing orders the following dangerous drugs:
      (i) hepatitis B vaccine;
      (ii) influenza vaccine;
      (iii) tuberculin purified protein derivative for tuberculosis testing; and
      (iv) pneumococcal polysaccharide vaccine.
(B) An agency that purchases, stores, or transports a vaccine or tuberculin under this section must ensure that any standing order for the vaccine or tuberculin:

(i) is signed and dated by the physician;
(ii) identifies the vaccine or tuberculin covered by the order;
(iii) indicates that the recipient of the vaccine or tuberculin has been assessed as an appropriate candidate to receive the vaccine or tuberculin and has been assessed for the absence of any contraindication;
(iv) indicates that appropriate procedures are established for responding to any negative reaction to the vaccine or tuberculin; and
(v) orders that a specific medication or category of medication be administered if the recipient has a negative reaction to the vaccine or tuberculin.

(3) Possession of certain dangerous drugs.

(A) In compliance with HSC §142.0063, an agency or its employees who are registered nurses or licensed vocational nurses may purchase, store, or transport for the purpose of administering to their home health or hospice patients, in accordance with subparagraph (C) of this paragraph, the following dangerous drugs:

(i) any of the following items in a sealed portable container of a size determined by the dispensing pharmacist:
   (I) 1,000 milliliters of 0.9% sodium chloride intravenous infusion;
   (II) 1,000 milliliters of 5.0% dextrose in water injection; or
   (III) sterile saline; or

(ii) not more than five dosage units of any of the following items in an individually sealed, unused portable container:
   (I) heparin sodium lock flush in a concentration of 10 units per milliliter or 100 units per milliliter;
   (II) epinephrine HCl solution in a concentration of one to 1,000;
   (III) diphenhydramine HCl solution in a concentration of 50 milligrams per milliliter;
   (IV) methylprednisolone in a concentration of 125 milligrams per two milliliters;
   (V) naloxone in a concentration of one milligram per milliliter in a two-milliliter vial;
   (VI) promethazine in a concentration of 25 milligrams per milliliter;
   (VII) glucagon in a concentration of one milligram per milliliter;
   (VIII) furosemide in a concentration of 10 milligrams per milliliter;
   (IX) lidocaine 2.5% and prilocaine 2.5% cream in a five-gram tube; or
   (X) lidocaine HCL solution in a concentration of 1% in a two-milliliter vial.

(B) An agency or the agency's authorized employees may purchase, store, or transport dangerous drugs in a sealed portable container only if the agency has established policies and procedures to ensure that:

(i) the container is handled properly with respect to storage, transportation, and temperature stability;
(ii) a drug is removed from the container only on a physician's written or oral order;
(iii) the administration of any drug in the container is performed in accordance with a specific treatment protocol; and
(iv) the agency maintains a written record of the dates and times the container is in the possession of a registered nurse or licensed vocational nurse.

(C) An agency or the agency's authorized employee who administers a drug listed in subparagraph (A) of this paragraph may administer the drug only in the client's residence under physician's orders in connection with the provision of emergency treatment or the adjustment of:

(i) parenteral drug therapy; or
(ii) vaccine or tuberculin administration.
(D) If an agency or the agency's authorized employee administers a drug listed in subparagraph (A) of this paragraph pursuant to a physician's oral order, the agency must receive a signed copy of the order:

(i) not later than 24 hours after receipt of the order, reduce the order to written form and send a copy of the form to the dispensing pharmacy by mail or facsimile transmission; and

(ii) not later than 20 days after receipt of the order, send a copy of the order as signed by and received from the physician to the dispensing pharmacy.

(E) A pharmacist that dispenses a sealed portable container under this subsection will ensure that the container:

(i) is designed to allow access to the contents of the container only if a tamper-proof seal is broken;

(ii) bears a label that lists the drugs in the container and provides notice of the container's expiration date, which is the earlier of:

(I) the date that is six months after the date on which the container is dispensed; or

(II) the earliest expiration date of any drug in the container; and

(iii) remains in the pharmacy or under the control of a pharmacist, registered nurse, or licensed vocational nurse.

(F) If an agency or the agency's authorized employee purchases, stores, or transports a sealed portable container under this subsection, the agency must deliver the container to the dispensing pharmacy for verification of drug quality, quantity, integrity, and expiration dates not later than the earlier of:

(i) the seventh day after the date on which the seal on the container is broken; or

(ii) the date for which notice is provided on the container label.

(G) A pharmacy that dispenses a sealed portable container under this section is required to take reasonable precautionary measures to ensure that the agency receiving the container complies with subparagraph (F) of this paragraph. On receipt of a container under subparagraph (F) of this paragraph, the pharmacy will perform an inventory of the drugs used from the container and will restock and reseal the container before delivering the container to the agency for reuse.

DIVISION 5
§97.321 ~ STANDARDS FOR BRANCH OFFICES

(a) A branch office operates as a part of the parent agency and must comply with the same regulations as the parent agency. The parent agency is responsible for ensuring that its branches comply with licensing standards.

(b) A branch office providing licensed and certified home health services must comply with the standards for certified agencies in §97.402.

(c) The service area of a branch office must be located within the parent agency's service area.

(1) A branch office must not provide services outside its licensed service area.

(2) A branch office must maintain adequate staff to provide services and to supervise the provision of services within the service area.

(3) A branch office may expand its service area at any time during the licensure period.

(A) Unless exempted under subparagraph (B) of the paragraph, a branch office must submit to DADS a written notice to expand its service area at least 30 days before the expansion. The notice must include:

(i) revised boundaries of the branch office's original service area;

(ii) the effective date of the expansion; and

(iii) an updated list of management and supervisory personnel including names, if changes are made.
(B) An agency is exempt from the 30-day written notice requirement under subparagraph (A) of this paragraph if DADS determines an emergency exists that would impact client health and safety. An agency must notify DADS immediately of a possible emergency. DADS determines if an exemption can be granted.

(4) A branch office may reduce its service area at any time during the licensure period by sending DADS written notification of the reduction, revised boundaries of the branch office’s original service area, and the effective date of the reduction.

(d) A parent agency and a branch office providing home health or personal assistance services must meet the following requirements:

(1) The parent agency administrator or alternate administrator, or supervising nurse or alternate supervising nurse must conduct an on-site supervisory visit to the branch office at least monthly. The parent agency may visit the branch office more frequently considering the size of the service area and the scope of services provided by the parent agency. The supervisory visits must be documented and include the date of the visit, the content of the consultation, the individuals in attendance, and the recommendations of the staff.

(2) The original active clinical record must be kept at the branch office.

(3) The parent agency must approve all branch office policies and procedures. This approval must be documented and filed in the parent and branch offices.

(e) DADS issues or renews a branch office license for applicants who meet the requirements of this section.

(1) Issuance or renewal of a branch office license is contingent upon compliance with the statute and this chapter by the parent agency and branch office.

(2) DADS may take enforcement action against a parent agency license for a branch office’s failure to comply with the statute or this chapter in accordance with Subchapter F.

(3) Revocation, suspension, denial, or surrender of a parent agency license will result in the same revocation, suspension, denial, or surrender of a branch office licenses of the parent agency.

(f) A branch office may offer fewer health services or categories than the parent office but may not offer health services or categories that are not also offered by the parent agency.

§97.322 ~ STANDARDS FOR ALTERNATE DELIVERY SITES

(a) An alternate delivery site must comply with §97.403.

(b) An alternate delivery site must independently meet §97.403(c), (f)(1), and (i), and §97.301.

(c) An alternate delivery site must be established within the parent agency's service area.

(1) An alternate delivery site must not provide services outside its licensed service area.

(2) An alternate delivery site must maintain adequate staff to provide services and to supervise the provision of services within the service area.

(3) An alternate delivery site may expand its service area at any time during the licensure period.

(A) Unless exempted under subparagraph (B) of this paragraph, an alternate delivery site must submit to DADS a written notice to expand its service area at least 30 days before the expansion. The notice must include:

(i) revised boundaries of the alternate delivery site’s original service area;

(ii) the effective date of the expansion; and

(iii) an updated list of management and supervisory personnel including names, if changes are made.

(B) An agency is exempt from the 30-day written notice requirement under subparagraph (A) of this paragraph if DADS determines that an emergency exists that would impact client health and safety. An agency must notify DADS immediately of a possible emergency. DADS determines if an exemption can be granted.

(4) An alternate delivery site may reduce its service area at any time during the licensure period by sending DADS written notification of the reduction, revised boundaries of the alternate delivery site’s original service area, and the effective date of the reduction.
(d) A parent agency and an alternate delivery site must meet the following requirements:
   (1) The parent agency administrator or alternate administrator, or supervising nurse or alternate supervising nurse must conduct an on-site supervisory visit to the alternate delivery site at least monthly. The parent agency may visit the alternate delivery site more frequently considering the size of the service area provided by the parent agency. The supervisory visits must be documented and include the date of the visit, the content of the consultation, the individuals in attendance, and the recommendations of the staff.
   (2) The original active clinical record must be kept at the alternate delivery site.
   (3) The parent agency must approve all alternate delivery site policies and procedures. This approval must be documented and filed in the parent and alternate delivery sites.

(e) DADS issues or renews an alternate delivery site license for applicants who meet the requirements of this section.
   (1) Issuance or renewal of an alternate delivery site license is contingent upon compliance with the statute and this chapter by the parent agency and alternate delivery site.
   (2) DADS may take enforcement action against a parent agency license for an alternate delivery site's failure to comply with the statute or this chapter in accordance with Subchapter F.
   (3) Revocation, suspension, denial or surrender of a parent agency license will result in the same revocation, suspension, denial or surrender of all alternate delivery site licenses of the parent agency.

**SUBCHAPTER D**

§97.401 ~ **STANDARDS SPECIFIC TO LICENSED HOME HEALTH SERVICES (LHHS)**

(a) In addition to the standards in Subchapter C, an agency providing LHHS must also meet the standards of this section.

(b) The agency must accept a client for home health services based on a reasonable expectation that the client's medical, nursing, and social needs can be met adequately in the client's residence. An agency has made a reasonable expectation that it can meet a client's needs if, at the time of the agency's acceptance of the client, the client and the agency have agreed as to what needs the agency would meet; for instance, the agency and the client could agree that some needs would be met but not necessarily all needs.

   (1) The agency must start providing licensed home health services to a client within a reasonable time after acceptance of the client and according to the agency's policy. The initiation of licensed home health services must be based on the client's health service needs.
   (2) An initial health assessment must be performed in the client's residence by the appropriate health care professional prior to or at the time that licensed home health services are initially provided to the client. The assessment must determine whether the agency has the ability to provide the necessary services.

   (A) If a practitioner has not ordered skilled care for a client, then the appropriate health care professional must prepare a care plan. The care plan must be developed after consultation with the client and the client's family and must include services to be rendered, the frequency of visits or hours of service, identified problems, method of intervention, and projected date of resolution. The care plan must be reviewed and updated by all appropriate staff members involved in client care at least annually, or more often as necessary to meet the needs of the client.
   (B) If a practitioner orders skilled treatment, then the appropriate health care professional must prepare a plan of care. The plan of care must be signed and approved by a practitioner in a timely manner. The plan of care must be developed in conjunction with agency staff and must cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits at the time of admission, prognoses, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, and any other appropriate items. The appropriate health
care personnel must perform services as specified in the plan of care. The plan of care must be revised as necessary, but it must be reviewed and updated at least every six months.

(c) Agency staff must provide at least one home health service.

(d) All services must be provided and supervised by qualified personnel. The appropriate licensed health care professional must be available to supervise as needed, when services are provided. If medical social service is provided, the social worker must be licensed in the state of Texas to provide social work services.

(e) All staff providing services, delegation, and supervision must be employed by or be under contract with the agency.

(f) An agency is not required to employ home health aides. If an agency employs home health aides, the agency must comply with §97.701.

(g) Unlicensed personnel employed by an agency to provide licensed home health services must:
   (1) have demonstrated competency in the task assigned when competency cannot be determined through education and experience; and
   (2) be at least 18 years of age or, if under 18 years of age, be a high school graduate or enrolled in a vocational education program.

§97.402 ~ STANDARDS SPECIFIC TO LICENSED AND CERTIFIED HOME HEALTH SERVICES

(a) In addition to the standards in Subchapter C, an agency providing licensed and certified home health services must comply with the requirements of the SSA and the regulations in 42 CFR Part 484.

(b) An agency providing licensed and certified home health services that plans to implement a home health aide training and competency evaluation program must meet the requirements in §97.701(d)-(f).

(c) An agency providing licensed and certified home health services that plans to implement a competency evaluation program must comply with §97.701(f).

(d) An agency providing licensed and certified home health services may not use an individual as a home health aide unless:
   (1) the individual has met the federal requirements under subsection (a) of this section;
   (2) the individual qualifies as a home health aide on the basis of a:
      (A) training and competency evaluation program, and the program meets the requirements of subsection (b) of this section; or
      (B) competency evaluation program, and the program meets the requirements of subsection (c) of this section; or
   (3) the individual is a licensed health care provider.

(e) Since the individual's most recent completion of a training and competency evaluation program or a competency evaluation program, if there has been a period of 24 consecutive months during which the individual has not furnished home health services, the individual will not be considered as having completed a training and competency evaluation program or a competency evaluation program.

§97.403 ~ STANDARDS SPECIFIC TO AGENCIES LICENSED TO PROVIDE HOSPICE SERVICES

(a) In addition to complying with the minimum standards in Subchapter C, an agency that is licensed to provide hospice services, must also comply with the standards of this section. If licensed and certified to provide hospice services, an agency must also comply with the requirements of the SSA and the regulations in 42 CFR Part 418.

(b) A person who is not licensed to provide hospice services may not use the word ‘hospice’ in a title or description of a facility, organization, program, service provider or services or use any other words, letters, abbreviations, or insignia indicating or implying that the person holds a license to provide hospice services.
(c) A hospice must adopt and enforce a written policy relating to the provision of hospice services in accordance with this section. All covered services must be available 24 hours a day, seven days a week, during the last stages of illness, during death, and during bereavement, to the extent necessary for the palliation and management of terminal illness and related conditions. Services include, at a minimum:
   (1) nursing;
   (2) medical social services;
   (3) counseling;
   (4) volunteer care;
   (5) bereavement counseling;
   (6) coordination of short-term inpatient care;
   (7) physician services; and
   (8) medications.

(d) The hospice must have a medical director who:
   (1) is a hospice employee, independent contractor, or volunteer;
   (2) is a doctor of medicine or osteopathy licensed in the State of Texas; and
   (3) assumes responsibility for the medical component of the hospice’s client care program.

(e) The hospice must designate an interdisciplinary team or teams composed of individuals who provide or supervise the care and services offered by the hospice.
   (1) The interdisciplinary team or teams must include at least the following individuals who are employees of the hospice:
      (A) a physician;
      (B) a registered nurse;
      (C) a social worker; and
      (D) a counselor.
   (2) The interdisciplinary team must be responsible for the:
      (A) participation in the establishment of the plan of care;
      (B) provision and supervision of hospice care and services;
      (C) periodic reviews and updates of the plan of care for each client receiving hospice care; and
      (D) establishment of policies governing the day to day provision of hospice care and services.
   (3) If the hospice has more than one interdisciplinary team, the hospice must designate in advance the team it chooses to execute the functions described in paragraph (2)(D) of this subsection.
   (4) The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each client.

(f) Subject to subsections (m) and (r) of this section, the hospice may arrange for another individual or entity to furnish services to the hospice clients. If services are provided under arrangement, the hospice must meet the following standards.
   (1) The hospice program must assure the continuity of client and family care in home and outpatient and inpatient settings.
   (2) The hospice must have a contract for the provision of arranged services. The contract must be signed by authorized representatives of the hospice as well as the contracting party. The contract must include the following:
      (A) identification of the services to be provided;
      (B) a stipulation that services may be provided only with the express authorization of the hospice;
      (C) the manner in which the contracted services are coordinated, supervised, and evaluated by the hospice;
      (D) the delineation of the role(s) of the hospice and the contractor in the admission process, client and family health assessment, and the interdisciplinary team case conferences;
      (E) requirements for documentation that services are furnished in accordance with the agreement; and
(F) the qualifications of the personnel providing the services.

(3) The hospice must retain professional management responsibility for arranged services and ensure they are furnished in a safe and effective manner by persons meeting the qualifications under this chapter, and in accordance with the client's plan of care and the other requirements of this subsection.

(4) The hospice must retain responsibility for payment for services.

(5) The hospice must ensure that inpatient care is furnished only in a licensed facility that meets the requirements of subsection (w) of this section, and the hospice's arrangement for inpatient care must be described in a contract and must meet the requirements of paragraph (2) of this subsection. The contract, at minimum, must meet the following requirements:
(A) that the hospice furnishes to the inpatient provider a copy of the client's plan of care and specifies the inpatient services to be furnished;
(B) that the inpatient provider has established policies consistent with those of the hospice and agrees to abide by the client care protocols established by the hospice for its clients;
(C) that the medical record includes a record of all inpatient services and events, and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;
(D) include the party responsible for implementation of the provisions of the contract and;
(E) that the hospice retains responsibility for appropriate hospice care training (to include palliative and end of life issues) of the personnel who provide the care under the agreement.

(g) Prior to the start of care, the hospice physician or registered nurse must make an initial health assessment visit to determine the immediate care and support needs of the client.
(1) The hospice physician or registered nurse must contact the client or client's representative within 24 hours of receiving the physician's referral for hospice care to schedule an appointment for the initial health assessment.
(2) The initial health assessment visit must be held within 48 hours after the hospice's receipt of the physician's referral for hospice care, unless ordered otherwise.
(3) After the initial health assessment is completed, services approved by the physician may be rendered.

(h) The hospice must perform and make available to each client admitted for hospice services a client-specific comprehensive health assessment that identifies the client's need for hospice care and the client's need for medical, nursing, social, emotional, and spiritual care which includes, but is not limited to, the palliation and management of the terminal illness and related conditions and support services for clients and their families.
(1) The hospice must complete the comprehensive health assessment in a timely manner consistent with the client's immediate needs, but no later than seven calendar days after the start of hospice care.
(2) The comprehensive health assessment must include:
(A) input from the appropriate interdisciplinary team members and an assessment of:
   (i) each client's physical condition, including functional ability and nutritional status;
   (ii) each client's pain and other symptoms and the management of discomfort and symptom relief;
   (iii) the client's and the client's family's social and emotional well-being;
   (iv) the client's spiritual orientation and needs;
   (v) the survivor risk factors to be considered in developing the bereavement care plan; and
   (vi) any other information necessary to develop an effective, interdisciplinary plan of care;
(B) a review, repeated as necessary, of the client's medication list. The medication list must include all prescription and over-the-counter drugs to assure that all drugs are indicated and to identify any potential problems including, but not limited to:
   (i) ineffective drug therapy;
   (ii) significant side effects;
(iii) significant drug interactions;
(iv) significant drug and food interactions;
(v) duplicate drug therapy; and
(vi) noncompliance with drug therapy; and
(C) a system of measures that captures significant outcomes that are essential to optimal hospice care, that are used in the care planning and coordination of services, and that are an essential part of the hospice's quality assessment and performance improvement program. The measures include, but are not limited to:

(i) pain;
(ii) nutritional status;
(iii) continence;
(iv) respiratory comfort;
(v) infections;
(vi) skin integrity;
(vii) level of consciousness;
(viii) anxiety;
(ix) depression;
(x) client emotional well being and satisfaction, including anxiety and depression;
(xi) spiritual well being;
(xii) social well being;
(xiii) family knowledge and understanding; and
(xiv) client and family satisfaction.

(3) The comprehensive health assessment must be updated and revised:

(A) as frequently as the condition of the client requires, as determined by:
   (i) changes in the client's physical, social, emotional or spiritual status;
   (ii) family environment; or
   (iii) suboptimal response to care, treatments or therapies; and
(B) within 24 hours of the client's return home from an inpatient stay.

(i) A written plan of care must be established and maintained for each client admitted to the hospice program, and the care provided to a client must be in accordance with the plan. The plan of care must specify the care and services necessary to meet the client-specific needs identified in the comprehensive health assessment described in subsection (h) of this section, include all client care orders, reflect planned interventions for problems identified, and ensure that care and services are appropriate to the severity level of each client's and the client's family's specific needs.

(1) The plan must be established by the attending physician, the medical director or physician designee, and interdisciplinary team prior to providing care.

(2) The plan must be reviewed and updated as necessary, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary team. These reviews must be documented. An updated plan must include information from the client's comprehensive health assessment and information concerning the client's progress toward outcomes as specified in the plan.

(3) The plan must include:

(A) a comprehensive health assessment of the client's needs and identification of the services including the management of pain and symptom relief. The plan must state in detail the scope and frequency of services that are needed to meet the client's and family's needs;
(B) interventions to facilitate the management of pain and symptoms;
(C) frequency and mix of services necessary to meet the client and family specific needs identified in the comprehensive health assessment;
(D) measurable outcomes that the hospice anticipates will occur as a result of implementing and coordinating the plan of care;
(E) drugs and treatments necessary to meet the needs of the patient as identified in the health assessment;
(F) medical supplies and appliances necessary to meet the needs of the client identified in the health assessment; and
(G) client and family understanding, agreement, and involvement with the plan as desired.

(j) The interdisciplinary team may reassess the client for an appropriate level of care, as long as the reassessment does not reduce core services.

(k) The hospice must inform the client of the availability of short-term inpatient care for pain control, management, and respite purposes and the names of the facilities with which the agency has a contract agreement.

(l) The hospice must document reasonable efforts to arrange for visits of clergy and other members of spiritual and religious organizations in the community to clients who request such visits and must advise all clients of this opportunity.

(m) The hospice must ensure that substantially all the core services described in subsections (n) - (q) of this section are routinely provided directly by hospice employees. The hospice may use contracted staff if necessary to supplement its employees in order to meet the needs of clients during periods of peak client loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and assure that the qualifications of staff and services provided meet the requirements specified in subsections (n) - (q) of this section.

(n) The hospice must provide nursing care and services by or under the supervision of a registered nurse.
   (1) Nursing services must be directed and staffed to assure that the nursing needs of the clients are met.
   (2) Client care responsibilities of nursing personnel must be specified.
   (3) Services must be provided in accordance with recognized standards of practice.

(o) Medical social services must be provided by a social worker who is licensed in the state of Texas to provide social work services and must be under the direction of a physician.

(p) In addition to palliation and management of terminal illness and related conditions, hospice physicians, including physician member(s) of the interdisciplinary team, must meet the general medical needs of the clients to the extent that these needs are not met by the attending physician. The hospice physician may meet these requirements either by directly providing the services or through coordination with the attending physician. If the attending physician is unavailable, the hospice physician is responsible for the care of the client.

(q) Counseling services must be available to both the client and the family. Counseling includes dietary, spiritual, and any other counseling services for the client and family provided while the client is enrolled in the hospice program as well as bereavement counseling provided after the client's death.
   (1) Bereavement counseling service must be available to the family.
      (A) There must be an organized program for the provision of bereavement services under the supervision of the interdisciplinary team, a social worker, a mental health professional, a counselor, or other person with documented evidence of training and experience in dealing with bereavement and structured training in bereavement counseling. Persons providing bereavement counseling must have documented evidence of training in personnel folders.
      (B) The plan of care for these services must reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery. Services must be provided up to one year following the death of the client.
   (2) Dietary counseling must be planned by a registered or licensed dietitian, a person who is eligible for registration by the American Dietetic Association, or an individual who has documented equivalency in education or training. Dietary counseling must meet specific client needs as described in the client's plan of care. Although a dietitian need not be a full-time
employee, there must be a record of this individual's credentials on file in the hospice. Dietary counseling must be supervised by a registered or licensed dietitian or a registered nurse.

(3) Spiritual counseling must include notice to clients as to the availability of clergy as required under subsection (l) of this section. Spiritual counseling may be conducted by clergy or other members of a spiritual and religious organization of the client's choice.

(4) Counseling may be provided by other members of the interdisciplinary team as well as by other professionals qualified by license or education to perform the type of counseling provided as determined by the hospice. Counseling, other than bereavement, dietary, or spiritual must be provided by persons qualified by license or education to perform the type of counseling to be provided in accordance with the client's plan of care. The counseling requirements do not preclude other members of the interdisciplinary team or other professionals from serving in the capacity of counselor. Nonprofessional volunteers may be used for listening and social interaction with clients.

(r) The hospice must ensure that the services described in subsections (s) - (v) of this section are provided directly by hospice employees or under arrangements made by the hospice as specified in subsection (f) of this section. The hospice must maintain a system of communication and integration of services, whether provided directly or under arrangement, that ensures the identification of client needs and the ongoing liaison of all disciplines providing care.

(s) Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, must be offered in a manner consistent with accepted standards of practice.

(t) Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the clients. A home health aide must meet the training and competency evaluation requirements or the competency evaluation requirements as specified in §97.701(d) - (f).

(1) A registered nurse must visit the residence site no less frequently than every two weeks when aide services are being provided, and the visit must include an assessment of the aide services. The aide need not be present at each supervisory visit.

(2) Written instructions for client care must be prepared by a registered nurse.

(u) Medical supplies and appliances, including medications, must be provided as needed for the palliation and management of the terminal illness and related conditions.

(1) All medications must be administered in accordance with accepted standards of practice.

(2) The hospice must have and enforce a policy for the disposal of controlled medications maintained in the client's residence when those medications are no longer needed by the client.

(3) Medications must be administered only by the following individuals:
   (A) a licensed nurse or physician;
   (B) a permitted home health medication aide;
   (C) the client if his or her attending physician has approved;
   (D) another individual acting in accordance with applicable federal and state laws, or as specified in the rules adopted by the BON in:
      (i) 22 TAC, Chapter 224; and
      (ii) 22 TAC, Chapter 225.

(4) The persons who are authorized to administer medications must be specified in the client's plan of care.

(v) Inpatient care must be available for pain control, symptom management, and respite purposes.

(1) Inpatient care must be provided by a licensed freestanding hospice or a hospital or nursing facility that meets the requirements specified in subsection (w)(1) and (5) of this section.

(2) A hospice must develop, implement, maintain and evaluate an ongoing, comprehensive integrated self assessment of the quality and appropriateness of care provided, including inpatient care, home care, and care provided under arrangement. The findings must be documented and used by the hospice to correct identified problems and to revise hospice
policies if necessary. Corrective action must be taken and tracked to ensure that improvements are sustained over time.

(A) The hospice’s quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to demonstrate improved performance with regard to:

(i) the system of measures that the hospice uses to determine if individual and aggregate outcomes are achieved compared to a previous time period;

(ii) current clinical practice guidelines and professional practice standards applicable to hospice care;

(iii) utilization data, as appropriate. This includes data, such as numbers of staff, types of visits, and inpatient care; and

(iv) effectiveness and safety of services. This includes services such as parenteral therapy or infusion controlling devices, if provided; competency of clinical staff; promptness of service delivery; and appropriateness of responses to client and family problems.

(B) The hospice must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes. The hospice must immediately correct identified problems that directly or potentially threaten the care and safety of clients.

(w) A freestanding hospice that provides inpatient care directly must comply with the following standards in addition to the standards in subsections (a) - (v) of this section.

(1) The hospice must have on-site 24-hour nursing service provided by registered nurses and licensed vocational nurses sufficient in number to meet total nursing needs and in accordance with the client’s plan of care.

(A) Each client must receive treatments, medications, and diet as prescribed, and must be kept comfortable, clean, well groomed, and protected from accident, injury, and infection.

(B) Each shift must include a registered nurse that provides and supervises direct client care.

(2) In addition to §97.256, a freestanding hospice facility must address the following core functions of emergency management in its written emergency preparedness and response plan: direction and control, communication, resource management, sheltering in place, evacuation, transportation, and training. The facility must maintain documentation of compliance with this paragraph.

(A) The portion of the plan on direction and control must:

(i) designate a person by position, and at least one alternate, to be in charge during implementation of an emergency response plan, with authority to execute a plan to evacuate or shelter in place;

(ii) include procedures the facility will use to maintain continuous leadership and authority in key positions;

(iii) include procedures the facility will use to activate a timely response plan based on the types of disasters identified in the risk assessment;

(iv) include procedures the facility will use to meet staffing requirements;

(v) include procedures the facility will use to warn or notify facility staff about internal and external disasters, including during off hours, weekends, and holidays;

(vi) include procedures the facility will use to maintain a current list of who the hospice will notify once warning of a disaster is received;

(vii) include procedures the facility will use to alert critical facility personnel once a disaster is identified; and

(viii) include procedures the facility will use to maintain a current 24-hour contact list for all staff.
(B) The portion of the plan on communication must include procedures:
(i) for continued communication, including procedures to maintain contact during an evacuation, with critical personnel and with all vehicles traveling in an evacuation caravan;
(ii) to maintain an accessible, current list of the phone numbers of client family members, local shelters, prearranged receiving facilities, the local emergency management coordinator, emergency medical services, other healthcare providers, and local, state, and federal emergency management agencies;
(iii) to notify staff, clients, families of clients, families of critical staff, prearranged receiving facilities, and others of an evacuation or the plan to shelter in place;
(iv) to provide a contact number for out-of-town family members to call for information; and
(v) to use the web-based system designed for facilities regulated by DADS to help each other relocate and track clients during disasters that require mass evacuations.

(C) The portion of the plan on resource management must include procedures:
(i) to maintain contracts and agreements with multiple vendors for supplies and transportation;
(ii) to develop accurate, detailed, and current checklists of essential supplies, staff, equipment, and medications;
(iii) to designate responsibility for completing the checklists during disaster operations;
(iv) for the safe and secure transportation of adequate amounts of food, water, medications, and critical supplies and equipment during an evacuation; and
(v) to maintain a supply of sufficient resources for at least seven days to shelter in place, which must include:
   (I) emergency power, including backup generators and accounts for maintaining a supply of fuel;
   (II) potable water in an amount based on population and location;
   (III) the types and amounts of food for the number and types of clients served;
   (IV) extra pharmacy stocks of common medications; and
   (V) extra medical supplies and equipment, such as oxygen, linens, and any other vital equipment.

(D) The portion of the plan on sheltering in place must:
(i) be developed using information about the building’s construction and Life Safety Code systems;
(ii) describe the criteria to be used to decide whether to shelter in place versus evacuate;
(iii) include procedures to assess whether the building is strong enough to withstand the various types of possible disasters and to identify the safest areas of the building;
(iv) include procedures to secure the building against damage;
(v) include procedures for collaborating with the local emergency management agency, fire, police, and Emergency Management System (EMS) agencies regarding the decision to shelter in place;
(vi) include procedures to assign each task in the sheltering plan to facility staff;
(vii) describe procedures to shelter in place that allow the facility to maintain 24-hour operations for a minimum of seven days to maintain continuity of care for the number and types of clients served; and
(viii) include procedures to provide for building security.

(E) The portion of the plan on evacuation must:
(i) include contracts with prearranged receiving facilities to provide hospice in-patient care, with at least one facility located at least 50 miles away;
(ii) include procedures to identify and follow evacuation and alternative routes, and to notify the proper authorities of the decision to evacuate;
(iii) include procedures to protect and transport client records and to match them to each client;
(iv) include procedures to maintain a checklist of items to be transported with clients, including medications and assistive devices, and how the items will be matched to each client;
(v) include staffing procedures the facility will use to ensure that staff accompany evacuating clients;
(vi) include procedures to identify and assign staff responsibilities, including how clients will be cared for during evacuations, and a backup plan for lack of sufficient staff;
(vii) include procedures facility staff will use to account for all individuals in the building during the evacuation and to track all individuals evacuated;
(viii) include procedures for the use, protection, and security of the identifying information the facility will use to identify evacuated clients;
(ix) include procedures facility staff will follow if a client becomes ill or dies in route;
(x) include procedures to make a hospice counselor available to counsel evacuees;
(xi) include the facility's policy on whether family of staff and clients can shelter at the hospice and evacuate with staff and clients;
(xii) include procedures facility staff will use to determine when it is safe to return to the geographical area;
(xiii) include procedures to coordinate building security with the local emergency management agency;
(xiv) include procedures facility staff will use to determine if the building is safe for reoccupation; and
(xv) be approved by the local emergency management coordinator at least annually and when updated.

(F) The portion of the plan on transportation must:
(i) include procedures for using the facility's own vehicles or contracts with transportation vendors to provide suitable transportation for the type and number of clients being served;
(ii) require contracted transportation vendors to provide written statements that describe how the vendors plan to fulfill their commitments in case of a disaster;
(iii) include a backup plan facility staff will use in the event that the first transportation vendor overextended itself or does not show up; and
(iv) include procedures to coordinate the facility's transportation needs with the local emergency management coordinator.

(G) The portion of the plan on training must include:
(i) procedures that specify when and how the disaster response plan is reviewed with clients and family members;
(ii) procedures to review the role and responsibility of a client able to participate with the plan;
(iii) procedures for initial and periodic training for all facility staff to carry out the plan;
(iv) the frequency for conducting disaster drills and demonstrations to ensure staff are fully trained with respect to their duties under the plan; and
(v) procedures to conduct emergency response drills at least annually either in response to an actual disaster or in a planned drill, which may be in addition to, or combined with, the drills required by the Life Safety Code as specified in paragraph (4) of this subsection.
(3) The hospice must meet all federal, state, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating the following:
   (A) construction, maintenance, and equipment for the hospice;
   (B) sanitation;
   (C) communicable and reportable diseases; and
   (D) post-mortem procedures.
(4) Except as provided in this subsection, the hospice must meet National Fire Protection Association 101, Life Safety Code, 2000 Edition (NFPA 101), Chapter 18 and Chapter 19, published by NFPA. All documents published by the NFPA as referenced in this subsection may be obtained by writing the National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02169, or calling 1-800-344-3555.
   (A) DADS CMS waiver of specific provisions of the NFPA 101 required by this paragraph for a certified hospice for as long as CMS honors the waiver, if the waiver would not adversely affect the health and safety of the clients and rigid application of specific provisions of the NFPA 101 would result in unreasonable hardship for the hospice. DADS may waive specific provisions of the NFPA 101 for a licensed hospice, if the waiver would not adversely affect the health and safety of the clients; and rigid application of specific provisions of the NFPA 101 would result in unreasonable hardship for the hospice.
   (B) Any existing facility of two or more stories that is not of fire-resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically disabled clients above the street-level floor unless the facility is one of the following construction types (as defined in the NFPA 101):
      (i) Type II (1,1,1)-protected noncombustible;
      (ii) fully-sprinklered Type II (0,0,0)-noncombustible;
      (iii) fully-sprinklered Type III (2,1,1)-protected ordinary;
      (iv) fully-sprinklered Type V (1,1,1)-protected wood frame; or
      (v) a facility that achieves a passing score on the Fire Safety Evaluation System (FSES) for Health Care Occupancies, NFPA 101A, Guide on Alternative Approaches to Life Safety, Chapter 4, Fire Safety Evaluation System for Health Care Occupancies, 2001 Edition published by the NFPA.
(5) The hospice must be designed and equipped for the comfort and privacy of each client and family member. The hospice must provide:
   (A) physical space for private client and family visiting;
   (B) accommodations for family members to remain with the client throughout the night;
   (C) accommodations for family privacy after a client's death;
   (D) decor that is homelike in design and function; and
   (E) accommodations where clients are permitted to receive visitors at any hour, including small children.
(6) Client rooms must be designed and equipped for adequate nursing care and the comfort and privacy of clients. Each client's room must:
   (A) be equipped with or conveniently located near toilet and bathing facilities;
   (B) be at or above grade level;
   (C) contain a suitable bed for each client and other appropriate furniture;
   (D) have closet space that provides security and privacy for clothing and personal belongings;
   (E) contain no more than four beds;
   (F) measure at least 100 square feet for a single room or 80 square feet for each client for a multiclient room; and
   (G) be equipped with a device for calling the staff member on duty.
(7) For an existing building, DADS recognizes the CMS waiver for the space and occupancy requirements of paragraph (6)(E) and (F) of this subsection for a certified hospice for as long as CMS honors the waiver, if DADS finds that the requirements would result in unreasonable hardship on the hospice if strictly enforced, and the waiver serves the particular needs of the clients and does not adversely affect their health and safety. For an existing building, DADS may waive the space and occupancy requirements of paragraph (6)(E) and (F) of this subsection for a licensed hospice for as long as it is considered appropriate, if it finds that the requirements would result in unreasonable hardship on the hospice if strictly enforced and the waiver serves the particular needs of the clients and does not adversely affect their health and safety.

(8) The hospice must provide bathroom facilities. The bathroom facilities must include the following:
(A) an adequate supply of hot water at all times for client use; and
(B) plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by clients.

(9) The hospice must have available at all times a quantity of linen essential for the proper care and comfort of clients. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(10) The hospice must make provisions for isolating clients with infectious diseases.

(11) The hospice must provide and supervise meal service and menu planning. The hospice must:
(A) serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;
(B) procure, store, prepare, distribute, and serve all food under sanitary conditions;
(C) have a staff member trained or experienced in food management or nutrition if the staff member responsible for dietary services is not a dietitian.
(i) The person must:
(I) be a graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or
(II) be a graduate of a state-approved course that provided 90 or more hours of classroom instruction in food service supervision and must have experience as a supervisor in a health care institution with consultation from a dietitian; or
(III) have training and experience in food service supervision and management in a military service equivalent in content to the program in this paragraph.
(ii) The staff member is responsible for:
(I) planning menus that meet the nutritional needs of each client. The menus must follow the orders of the client's physician and, to the extent medically possible, follow the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances, 10th ed., 1989, available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418). The menus must be approved by a licensed dietitian. The hospice must use written guidelines for substitutions that are approved by the licensed dietitian; and
(II) supervising the meal preparation and meal service that is conducted to ensure that the menu plan is followed; and
(D) have the menus for those clients who require medically prescribed special diets. The menus must be planned by a dietitian who monitors the preparation and serving of meals to ensure that the client accepts the special diet.
(12) The hospice must provide appropriate methods and procedures for dispensing and administering medications. Whether medications are obtained from community or institutional pharmacists or stocked by the facility, the facility must be responsible for medications for its clients, insofar as they are covered under the program, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate federal and state laws.

(A) The hospice must employ a licensed pharmacist or have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and record keeping of medications.

(B) A physician must order all medications for the client.

(C) If the medication order is verbal, the physician must give it only to a licensed nurse, pharmacist, or another physician.

(D) If the medication order is verbal, the individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.

(E) Medications must be administered only by one of the following individuals:
   (i) a licensed nurse or physician;
   (ii) a permitted home health medication aide or an employee as specified in the rules adopted by the BON in:
       (I) 22 TAC, Chapter 224; or
       (II) 22 TAC, Chapter 225; or
   (iii) the client if his or her attending physician has approved.

(F) The pharmaceutical service must have procedures for control and accountability of all medications throughout the facility. Medications must be dispensed in compliance with federal and state laws. Records of receipt and disposition of all controlled medications must be maintained in sufficient detail to enable an accurate reconciliation. The pharmacist must determine that medication records are in order and that an account of all controlled medications is maintained and reconciled.

(G) The labeling of medications must be based on currently accepted professional principles, and must include the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

(H) In accordance with state and federal laws, all medications must be stored in locked compartments under proper temperature controls and only authorized personnel must have access to the keys. Separately locked compartments must be provided for storage of controlled medications listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 USC §801 et seq. and other medications that are subject to abuse, except under single-unit package medication distribution systems in which the quantity stored is minimal and a missing dose is readily detected. An emergency medication kit must be kept readily available.

(I) Controlled medications no longer needed by the client must be disposed of in compliance with state requirements. The pharmacist and registered nurse must dispose of medications and prepare a record of the disposal.

§97.404 ~ Standards Specific to Agencies Licensed to Provide Personal Assistance Services

(a) In addition to meeting the standards in Subchapter C, an agency holding a license with the category of personal assistance services must meet the standards of this section.

(b) A person who is not licensed to provide personal assistance services under this chapter may not indicate or imply that the person is licensed to provide personal assistance services by the use of the words ‘personal assistance services’ or in any other manner.
(c) Personal assistance services as defined in §97.2 may be performed by an unlicensed person who is at least 18 years of age and has demonstrated competency, when competency cannot be determined through education and experience, to perform the tasks assigned by the supervisor. An unlicensed person who is under 18 years of age, is a high school graduate or is enrolled in a vocational educational program, and has demonstrated competency to perform the tasks assigned by the supervisor, may perform personal assistance services.

(d) The following tasks may be performed under a personal assistance services category:

1. personal care as defined in §97.2;
2. health-related tasks provided by unlicensed personnel that may be delegated by an RN or that an RN determines do not require delegation in accordance with the agency's written policy adopted, implemented, and enforced to ensure compliance with the rules adopted by the BON in 22 TAC, Chapter 225;
3. health-related tasks that are not the practice of professional nursing under the memorandum of understanding between DADS and BON; and
4. health-related tasks that are delegated by a physician under the Occupations Code, Chapter 157.

(e) The agency must ensure that when developing its operational policies, the policies are considerate of principles of individual and family choice and control, functional need, and accessible and flexible services.

(f) In addition to the client record requirements in §97.301(a)(9), the client file must include the following:

1. documentation of determination of services based on an on-site visit by the supervisor where services will be primarily delivered and records of supervisory visits, if applicable;
2. individualized service plan developed, agreed upon, and signed by the client or family and the agency. The individualized service plan must include, but not be limited to the following:
   A) types of services, supplies, and equipment to be provided;
   B) locations of services;
   C) frequency and duration of services;
   D) planned date of service initiation;
   E) charges for services rendered if the charges will be paid in full or in part by the client or significant others, or on request; and
   F) plan of supervision; and
3. documentation that the services have been provided according to the individualized service plan.

(g) In addition to the written policies required by §97.245 the agency must adopt and enforce a written policy addressing the supervision of personnel with input from the client or family on the frequency of supervision.

1. Supervision of personnel must be in accordance with the agency's policies and applicable state laws and rules, including rules adopted by the BON in 22 TAC, Chapter 225.
2. A supervisor must be a licensed nurse or have completed two years of full-time study at an accredited college or university. An individual with a high school diploma or GED may substitute one year of full-time employment in a supervisory capacity in a health care facility, agency, or community-based agency for each required year of college.
3. The client in a client managed attendant care program funded by DADS or the Department of Assistive and Rehabilitative Services is not required to meet the standard in paragraph (2) of this subsection.
(h) Tube feedings and medication administration through a permanently placed gastrostomy tube (g-tube) in accordance with subsection (d)(3) of this section may be performed by an unlicensed person only after successful completion of the training and competency program and procedures described in paragraphs (1) - (5) of this subsection.

(1) The training and competency program for the performance of g-tube feedings by an unlicensed person must be taught by an RN, physician, physician assistant (PA), or qualified trainer. A qualified trainer must:
(A) have successfully completed the training and competency program described in paragraphs (2) and (3) of this subsection taught by an RN, physician, or PA;
(B) have demonstrated upon return demonstration to an RN, physician, or PA the performance of the task and the ability to teach the task; and
(C) have been deemed competent by an RN, physician, or PA to train unlicensed personnel in these procedures. Documentation of competency to perform, train, and teach must be maintained in the employee's or contractor's file. Competency must be evaluated and documented by an RN, physician, or PA annually.

(2) The minimum training program must include:
(A) a description of the g-tube placement, including its purpose;
(B) infection control procedures and universal precautions to be utilized when performing g-tube feedings or medication administration through a g-tube;
(C) a description of conditions that must be reported to the client or the primary caregiver, or in the absence of the primary caregiver, to the agency administrator, supervisor, or the client's physician. The description of conditions must include a plan to be effected if the g-tube comes out or is not positioned correctly to ensure medical attention is provided within one hour;
(D) review of a written procedure for g-tube feeding or medication administration through a g-tube. The written procedure must be equivalent to current acceptable nursing standards of practice, including addressing the crushing of medications;
(E) conditions under which g-tube feeding or medication administration must not be performed; and
(F) demonstration of a g-tube feeding and medication administration to a client. If the trainee will become a qualified trainer, the demonstration must be done by the RN, PA, or physician. If the trainee will not become a qualified trainer, the demonstration may be done by an RN, PA, physician, or qualified trainer.

(3) The minimum competency evaluation must be documented and maintained in the employee's file and must include:
(A) a score of 100% on a written multiple choice test that consists of situational questions to include the criteria in paragraph (2)(A) - (E) of this subsection and an evaluation of the trainee's judgment and understanding of the essential skills, risks, and possible complications of a g-tube feeding or medication administration through a g-tube;
(B) a skills checklist demonstrating that the trainee has successfully completed the necessary skills for a g-tube feeding and medication administration via g-tube, and if the trainee will become a qualified trainer, the skills checklist must also demonstrate the ability to teach another person to perform the task. The skills checklist must be completed by an RN, physician, or PA if the trainee will become a qualified trainer. The skills checklist for a trainee who will not become a qualified trainer may be completed by an RN, PA, physician, or qualified trainer; and
(C) documentation of an accurate demonstration of the g-tube feeding and medication administration performed by the trainee as required by paragraph (2)(F) of this subsection. If the trainee will become a qualified trainer, documentation of competency to teach this task must be maintained in the file of the qualified trainer. The person responsible for the training of the trainee must document the successful demonstration of the g-tube feeding and
medication administration via g-tube by the trainee and the trainee’s competency to perform this task in the trainee's file.

(4) The client or primary caregiver must provide information on the client's g-tube feeding or medication administration to the agency supervisor. If the client is not capable of directing his or her own care, the client's primary caregiver must be present to instruct and orient the supervisor regarding the client's g-tube feeding and medication regime. A copy of the current regime including unique conditions specific to the client must be placed in the client's file by the agency supervisor and provided to the respite caregiver. The respite caregiver must be oriented by the client, the client's primary caregiver, or the agency supervisor. The supervisor of the delivery of these services must have successfully completed a training and competency program outlined in paragraphs (2) and (3) of this subsection or be a qualified trainer.

(5) Legend medications that are to be administered must be in a legally labeled container from a pharmacy that contains the name of the client. Instructions for dosages according to weight or age for over-the-counter drugs commonly given the client must be furnished by the primary caregiver to the respite caregiver performing the tube feeding or medication administration.

§97.405 ~ STANDARDS SPECIFIC TO AGENCIES LICENSED TO PROVIDE HOME DIALYSIS SERVICES

(a) License designation. An agency may not provide peritoneal dialysis or hemodialysis services in a client's residence, independent living environment, or other appropriate location unless the agency holds a license to provide licensed home health or licensed and certified home health services and designated to provide home dialysis services. In order to receive a home dialysis designation, the agency must meet the licensing standards specified in this section and the standards for home health services in accordance with Subchapter C and §97.401 except for §97.401(b)(2)(A) and (B). If there is a conflict between the standards specified in this section and those specified in Subchapter C, §97.401, the standards specified in this section will apply to the home dialysis services.

(b) Governing body. An agency must have a governing body. The governing body must appoint a medical director and the physicians who are on the agency's medical staff. The governing body must annually approve the medical staff policies and procedures. The governing body on a biannual basis must review and consider for approval continuing privileges of the agency's medical staff. The minutes from the governing body of the agency must be on file in the agency office.

(c) Qualifications and responsibilities of the medical director.

(1) Qualifications. The medical director must be a physician licensed in the State of Texas who:
   (A) is eligible for certification or is certified in nephrology or pediatric nephrology by a professional board; or
   (B) during the five-year period prior to September 1, 1996, served at least 12 months as director of a dialysis facility or program.

(2) Responsibilities. The medical director must:
   (A) participate in the selection of a suitable treatment modality for all clients;
   (B) assure adequate training of nurses in dialysis techniques;
   (C) assure adequate monitoring of the client and the dialysis process; and
   (D) assure the development and availability of a client care policy and procedures manual and its implementation.

(d) Personnel files. An agency must have individual personnel files on all physicians, including the medical director. The file must include the following:

(1) a curriculum vitae which documents undergraduate, medical school, and all pertinent post graduate training; and

(2) evidence of current licensure, and evidence of current United States Drug Enforcement Administration certification, Texas Department of Public Safety registration, and the board eligibility or certification, or the experience or training described in subsection (c)(1) of this section.
(e) Provision of services. An agency that provides home staff-assisted dialysis must, at a minimum, provide nursing services, nutritional counseling, and medical social service. These services must be provided as necessary and as appropriate at the client's home, by telephone, or by a client's visit to a licensed ESRD facility in accordance with this subsection. The use of dialysis technicians in home dialysis is prohibited.

(1) Nursing services.
   (A) A RN licensed by the State of Texas, who has at least 18 months experience in hemodialysis obtained within the last 24 months and has successfully completed the orientation and skills education described in subsection (f) of this section, must be available whenever dialysis treatments are in progress in a client's home. The agency administrator must designate a qualified alternate to this registered nurse.
   (B) Dialysis services must be supervised by an RN who meets the qualifications for a supervising nurse as set out in §97.244(c)(2).
   (C) Dialysis services must be provided by a qualified licensed nurse who:
      (i) is licensed as a registered or licensed vocational nurse by the State of Texas;
      (ii) has at least 18 months experience in hemodialysis obtained within the last 24 months; and
      (iii) has successfully completed the orientation and skills education described in subsection (f) of this section.

(2) Nutritional counseling. A dietitian who meets the qualifications of this paragraph must be employed by or under contract with the agency to provide services. A qualified dietitian must meet the definition of dietitian in §97.2 and have at least one year of experience in clinical nutrition after obtaining eligibility for registration by the American Dietetic Association, Commission on Dietetic Registration.

(3) Medical social services. A social worker who meets the qualifications established in this paragraph must be employed by or be under contract with the agency to provide services. A qualified social worker is a person who:
   (A) is currently licensed under the laws of the State of Texas as a social worker and has a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; or
   (B) has served for at least two years as a social worker, one year of which was in a dialysis facility or program prior to September 1, 1976, and has established a consultative relationship with a licensed master social worker.

(f) Orientation, skills education, and evaluation.

(1) All personnel providing dialysis in the home must receive orientation and skills education and demonstrate knowledge of the following:
   (A) anatomy and physiology of the normal kidney;
   (B) fluid, electrolyte, and acid-base balance;
   (C) pathophysiology of renal disease;
   (D) acceptable laboratory values for the client with renal disease;
   (E) theoretical aspects of dialysis;
   (F) vascular access and maintenance of blood flow;
   (G) technical aspects of dialysis;
   (H) peritoneal dialysis catheter, testing for peritoneal membrane equilibration, and peritoneal dialysis adequacy clearance, if applicable;
   (I) the monitoring of clients during treatment, beginning with treatment initiation through termination;
   (J) the recognition of dialysis complications, emergency conditions, and institution of the appropriate corrective action. This includes training agency personnel in emergency procedures and how to use emergency equipment;
   (K) psychological, social, financial, and physical complications of chronic dialysis;
(L) care of the client with chronic renal failure;
(M) dietary modifications and medications for the uremic client;
(N) alternative forms of treatment for ESRD;
(O) the role of renal health team members (physician, nurse, social worker, and dietitian);
(P) performance of laboratory tests (hematocrit and blood glucose);
(Q) the theory of blood products and blood administration; and
(R) water treatment to include:
   (i) standards for treatment of water used for dialysis as described in §3.2.1 (Hemodialysis Systems) and §3.2.2 (Maximum Level of Chemical Contaminants) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI), 3330 Washington Boulevard, Suite 500, Arlington, Virginia 22201. Copies of the standards are indexed and filed in DADS, 701 W. 51st Street, Austin, Texas 78751-2321, and are available for public inspection during regular working hours;
   (ii) systems and devices;
   (iii) monitoring; and
   (iv) risks to clients of unsafe water.

(2) The requirements for the orientation and skills education period for licensed nurses are as follows.
   (A) The agency must develop an 80-hour written orientation program that includes classroom theory and direct observation of the licensed nurse performing procedures on a client in the home.
      (i) The orientation program must be provided by a registered nurse qualified under subsection (e)(1) of this section to supervise the provision of dialysis services by a licensed nurse.
      (ii) The licensed nurse must pass a written skills examination or competency evaluation at the conclusion of the orientation program and prior to the time the licensed nurse delivers independent client care.
   (B) The licensed nurse must complete the required classroom component as described in paragraph (1)(A) - (E), (K) - (O), (Q) and (R) of this subsection and satisfactorily demonstrate the skills described in paragraph (1)(F) - (J) and (P) of this subsection. The orientation program may be waived by successful completion of the written examination as described in subparagraph (A)(ii) of this paragraph.
   (C) The supervising nurse or qualified designee must complete an orientation competency skills checklist for each licensed nurse to reflect the progression of learned skills, as described in subsection (f)(1) of this section.
   (D) Prior to the delivery of independent client care, the supervising nurse or qualified designee must directly supervise the licensed nurse for a minimum of three dialysis treatments and ensure satisfactory performance. Dependent upon the trainee’s experience and accomplishments on the skills checklist, additional supervised dialysis treatments may be required.
   (E) Continuing education for employees must be provided quarterly.
   (F) Performance evaluations must be done annually.
   (G) The supervising nurse or qualified designee must provide direct supervision to the licensed nurse providing dialysis services monthly or more often if necessary. Direct supervision means that the supervising nurse is on the premises but not necessarily immediately present where dialysis services are being provided.

(g) Hospital transfer procedure. An agency must establish an effective procedure for the immediate transfer to a local Medicare-certified hospital for clients requiring emergency medical care. The agency must have a written transfer agreement with such a hospital, or all physician members of the agency’s medical staff must have admitting privileges at such a hospital.
(h) Backup dialysis services. An agency that supplies home staff-assisted dialysis must have an agreement with a licensed ESRD facility to provide backup outpatient dialysis services.

(i) Coordination of medical and other information. An agency must provide for the exchange of medical and other information necessary or useful in the care and treatment of clients transferred between treating facilities. This provision must also include the transfer of the client care plan, hepatitis B status, and long-term program.

(j) Transplant recipient registry program. An agency must ensure that the names of clients awaiting cadaveric donor transplantation are entered in a recipient registry program.

(k) Testing for hepatitis B. An agency must conduct routine testing of home dialysis clients and agency employees to ensure detection of hepatitis B in employees and clients.

(1) An agency must offer hepatitis B vaccination to previously unvaccinated, susceptible new staff members in accordance with 29 CFR §1910.1030(f)(1)-(2).

(A) Staff vaccination records must be maintained in each staff member’s personnel file.

(B) New staff members providing home dialysis care must be screened for hepatitis B surface antigen (HBsAg) and the results reviewed prior to the staff providing client care, unless the new staff member provides the agency documentation of positive serologic response to hepatitis B vaccine.

(C) An agency must establish, implement, and enforce a policy for repeated serologic screening of staff. The repeated serologic screening must be based on each staff member’s HBsAg/antibody to HBsAg (anti-HBs), and must be congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 1993, published by the HHS. This document may be obtained by writing the HCSSA DADS, 701 W. 51st Street, Austin, Texas 78751-2321 or calling 438-3011 or writing the HHS at the Public Health Service, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Hospital Infection Program, Mail Stop C01, Atlanta, Georgia 30333, or calling 404-639-2318.

(2) With the advice and consent of a client’s nephrologist or attending physician, an agency must make the hepatitis B vaccine available to a client who is susceptible to hepatitis B, provided that the client has coverage or is willing to pay for vaccination.

(A) An agency must make available to clients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Candidates for home dialysis must be screened for HBsAg within one month before or at the time of admission to the agency.

(C) Repeated serologic screening must be based on the antigen or antibody status of the client.

(D) Monthly screening for HBsAg is required for clients whose previous test results are negative for HBsAg.

(E) Screening of HbsAg-positive or anti-HbsAg-positive clients may be performed on a less frequent basis, provided that the agency’s policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Diseases in the United States, 1993, published by the HHS.

(l) CPR certification. All direct client care employees must have current CPR certification.

(m) Initial admission assessment. Assessment of the client’s residence must be made to ensure a safe physical environment for the performance of dialysis. The initial admission assessment must be performed by a qualified registered nurse who meets the qualifications under subsection (e)(1)(A) of this section.

(n) Client long-term program. The agency must develop a long-term program for each client admitted to home dialysis. Criteria must be defined in writing and must provide guidance to the agency in the selection of clients suitable for home staff-assisted dialysis and in noting changes in a client’s condition that would require discharge from the program. For the purposes of this subsection, Long-term program means the written documentation of the selection of a suitable treatment modality and dialysis setting which has been selected by the client and the interdisciplinary team.
(o) Client history and physical. The agency must ensure that the history and physical is conducted upon the client's admission or no more than six months prior to the date of admission, then annually after the date of admission.

(p) Physician orders. If home staff-assisted dialysis is selected, the physician must prepare orders outlining specifics of prescribed treatment.
   (1) If these physician's orders are received verbally, they must be confirmed in writing within a reasonable time frame. An agency must adopt and enforce a policy on the time frame for the countersignature of a physician's verbal orders. Medical orders for home staff-assisted dialysis must be revised as necessary but reviewed and updated at least every six months.
   (2) The initial orders for home staff-assisted dialysis must be received prior to the first treatment and must cover all pertinent diagnoses, including mental status, prognosis, functional limitations, activities permitted, nutritional requirements, medications and treatments, and any safety measures to protect against injury. Orders for home staff-assisted dialysis must include frequency and length of treatment, target weight, type of dialyzer, dialysate, dialysate flow rate, heparin dosage, and blood flow rate, and must specify the level of preparation required for the caregiver, such as a licensed vocational nurse or registered nurse.

(q) Client care plan. The client care plan must be developed after consultation with the client and the client's family by the interdisciplinary team. The interdisciplinary team must include the physician, the registered nurse, the dietitian, and the qualified social worker responsible for planning the care delivered to the home staff-assisted dialysis patient.
   (1) The initial client care plan must be completed by the interdisciplinary team within ten calendar days after the first home dialysis treatment.
   (2) The client care plan must implement the medical orders and must include services to be rendered, such as the identification of problems, methods of intervention, and the assignment of health care personnel.
   (3) The client care plan must be in writing, be personalized for the individual, and reflect the ongoing medical, psychological, social, nutritional, and functional needs of the client, including treatment goals.
   (4) The client care plan must include written evidence of coordination with other service providers, such as dialysis facilities or transportation providers, as needed to assure the provision of safe care.
   (5) The client care plan must include written evidence of the client's or client's legal representative's input and participation, unless they refuse to participate. At a minimum, the client care plan must demonstrate that the content was shared with the client or the client's legal representative.
   (6) For non-stabilized clients, where there is a change in modality, unacceptable laboratory work, uncontrolled weight changes, infections, or a change in family status, the client care plan must be reviewed at least monthly by the interdisciplinary team. Evidence of the review of the client care plan with the client and the interdisciplinary team to evaluate the client's progress or lack of progress toward the goals of the care plan, and interventions taken when progress toward stabilization or the goals are not achieved, must be documented and included in the client record.
   (7) For a stable client, the client care plan must be reviewed and updated as indicated by any change in the client's medical, nutritional, or psychosocial condition or at least every six months. The long-term program must be revised as needed and reviewed annually. Evidence of the review of the client care plan with the client and the interdisciplinary team to evaluate the client's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, must be documented and included in the client record.

(r) Medication administration. Medications must be administered only by licensed personnel.
(s) Client records. In addition to the applicable information described in §97.301(a)(9), records of home staff assisted dialysis clients must include the following:

1. a medical history and physical;
2. clinical progress notes by the physician, qualified licensed nurse, qualified dietitian, and qualified social worker;
3. dialysis treatment records;
4. laboratory reports;
5. a client care plan;
6. a long-term program; and
7. documentation of supervisory visits.

(t) Water treatment.

1. Water used for dialysis purposes must be analyzed for chemical contaminants every six months. Additional chemical analysis must be conducted if test results exceed the maximum levels of chemical contaminants listed in §3.2.2 (Maximum Level of Chemical Contaminants) of the American National Standards for Hemodialysis Systems, March 1992 Edition, published by the AAMI. Copies of the standards are indexed and filed in the DADS, 701 W. 51st Street, Austin, Texas 78751-2321, and are available for public inspection during regular working hours.
2. Water used for dialysis must be treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques.
3. Water used to prepare dialysate must meet the requirements set forth in §3.2.1 (Hemodialysis Systems) and §3.2.2 (Maximum Level of Chemical Contaminants), March 1992 Edition, published by the AAMI. Copies of the standards are indexed and filed in the DADS, 701 W. 51st Street, Austin, Texas 78751-2321, and are available for public inspection during regular working hours.
4. Records of test results and equipment maintenance must be maintained at the agency.

(u) Equipment testing. An agency must adopt and enforce a policy to describe how the nurse will check the machine for conductivity, temperature, and pH prior to treatment, and describe the equipment required for these tests. The equipment must be available for use prior to each treatment. This policy must reflect current standards.

(v) Preventive maintenance for equipment. An agency must develop, and enforce a written preventive maintenance program to ensure client care related equipment receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently if recommended by the manufacturer. The preventive maintenance may be provided by agency or contract staff qualified by training or experience in the maintenance of dialysis equipment.

1. All equipment used by a client in home dialysis must be maintained free of defects, which could be a potential hazard to clients, the client’s family or agency personnel.
   A. Agency staff must be able to identify malfunctioning equipment and report such equipment to the appropriate agency staff. Malfunctioning equipment must be immediately removed from use.
   B. Written evidence of all preventive maintenance and equipment repairs must be maintained.
   C. After repairs or alterations are made to any equipment, the equipment must be thoroughly tested for proper operation before returning to service.
   D. An agency must comply with the Federal Food, Drug, and Cosmetic Act, 21 USC §360i(b), concerning reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of an agency client.

2. In the event that the water used for dialysis purposes or home dialysis equipment is found not to meet safe operating parameters, and corrections cannot be effected to ensure safe care promptly, the client must be transferred to a licensed hospital (if inpatient care is required) or licensed ESRD facility until such time as the water or equipment is found to be operating within safe parameters.
(w) Reuse or reprocessing of medical devices. Reuse or reprocessing of disposable medical devices, including but not limited to, dialyzers, end-caps, and blood lines must be in accordance with this subsection.

(1) An agency's reuse practice must comply with the American National Standard, Reuse of Hemodialyzers, 1993 Edition, published by the AAMI. An agency must adopt and enforce a policy for dialyzer reuse criteria (including any agency-set number of reuses allowed) which is included in client education materials.

(2) A transducer protector must be replaced when wetted during a dialysis treatment and must be used for one treatment only.

(3) Arterial lines may be reused only when the arterial lines are labeled to allow for reuse by the manufacturer and the manufacturer-established protocols for the specific line have been approved by the United States Food and Drug Administration.

(4) An agency must consider and address the health and safety of clients sensitive to disinfectant solution residuals.

(5) An agency must provide each client and the client's family or legal representative with information regarding the reuse practices of the agency, the opportunity to tour the reuse facility used by the agency, and the opportunity to have questions answered.

(6) An agency practicing reuse of dialyzers must:
   (A) ensure that dialyzers are reprocessed via automated reprocessing equipment in a licensed ESRD facility or a centralized reprocessing facility;
   (B) maintain responsibility and accountability for the entire reuse process;
   (C) adopt and enforce policies to ensure that the transfer and transport of used and reprocessed dialyzers to and from the client's home does not increase contamination of the dialyzers, staff, or the environment; and
   (D) ensure that DADS staff has access to the reprocessing facility as part of an agency inspection.

(x) Laboratory services. Provision of laboratory services must be as follows.

(1) All laboratory services ordered for the client by a physician must be performed by a laboratory which meets the CLIA 1988 and in accordance with a written arrangement or agreement with the agency. CLIA 1988 applies to all agencies with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) Copies of all laboratory reports must be maintained in the client's medical record.

(3) Hematocrit and blood glucose tests may be performed at the client's home in accordance with §97.284. Results of these tests must be recorded in the client's medical record and signed by the qualified licensed nurse providing the treatment. Maintenance, calibration, and quality control studies must be performed according to the equipment manufacturer's suggestions, and the results must be maintained at the agency.

(4) Blood and blood products must only be administered to dialysis clients in their homes by a licensed nurse or physician.

(y) Home dialysis supplies. Supplies for home dialysis must meet the following requirements.

(1) All drugs, biologicals, and legend medical devices must be obtained for each client pursuant to a physician's prescription in accordance with applicable rules of the Texas State Board of Pharmacy.

(2) In conjunction with the client's attending physician, the agency must ensure that there are sufficient supplies maintained in the client's home to perform the scheduled dialysis treatments and to provide a reasonable number of backup items for replacements, if needed, due to breakage, contamination, or defective products. All dialysis supplies, including medications, must be delivered directly to the client's home by a vendor of such products. However, agency personnel may transport prescription items from a vendor's place of business to the client's home.
for the client's convenience, so long as the item is properly labeled with the client's name and direction for use. Agency personnel may transport medical devices for reuse.

(z) Emergency procedures. The agency must adopt and enforce policies and procedures for medical emergencies and emergencies resulting from a disaster.

(1) Procedures must be individualized for each client to include the appropriate evacuation from the home and emergency telephone numbers. Emergency telephone numbers must be posted at each client's home and must include 911 if available, the number of the physician, the ambulance, the qualified registered nurse on call for home dialysis, and any other phone number deemed as an emergency number.

(2) The agency must ensure that the client and the client's family know the agency's procedures for medical emergencies and emergencies resulting from a disaster.

(3) The agency must ensure that the client and the client's family know the procedure for disconnecting the dialysis equipment.

(4) The agency must ensure that the client and the client's family know emergency call procedures.

(5) A working telephone must be available during the dialysis procedure.

(6) Depending on the kinds of medications administered, an agency must have available emergency drugs as specified by the medical director.

(7) In the event of a medical emergency or an emergency resulting from a disaster requiring transport to a hospital for care, the agency must assure the following:

(A) the receiving hospital is given advance notice of the client's arrival;

(B) the receiving hospital is given a description of the client's health status; and

(C) the selection of personnel, vehicle, and equipment are appropriate to effect a safe transfer.

§97.406 ~ STANDARDS FOR AGENCIES PROVIDING PSYCHOACTIVE SERVICES

An agency that provides skilled nursing psychoactive treatments must comply with the requirements of this section.

(1) An agency must adopt and enforce a written policy relating to the provision of psychoactive treatments consistent with this section.

(2) Skilled nursing psychoactive treatments must be under the direction of a physician. Psychoactive treatments may only be provided by a physician or a registered nurse.

(3) A registered nurse providing skilled nursing psychoactive treatments must have one of the following qualifications:

(A) a master's degree in psychiatric or mental health nursing;

(B) a bachelor's degree in nursing with one year of full-time experience in an active treatment unit in a mental health facility or outpatient clinic;

(C) a diploma or associate degree with two years of full-time experience in an active treatment unit in a mental health facility or outpatient clinic; or

(D) for a registered nurse for Medicare certified agencies, as allowed by the fiscal intermediary for Texas contracting with the HHS CMS.

(4) An agency must have written documentation that a registered nurse providing skilled nursing psychoactive treatments is qualified under paragraph (3) of this subsection.

(5) The initial health assessment of a client receiving skilled nursing psychoactive treatments must include:

(A) mental status including psychological and behavioral status;

(B) sensory and motor function;

(C) cranial nerve function;

(D) language function; and

(E) any other criteria established by an agency's policy.
§97.407 ~ STANDARDS FOR AGENCIES PROVIDING HOME INTRAVENOUS THERAPY

An agency furnishing intravenous therapy directly or under arrangement must comply with the following standards of care.

1. A physician's order must be written specifically for intravenous therapy.

2. Intravenous therapy must be provided by a licensed nurse.

3. To ensure that prescribed care is administered safely, a licensed nurse must have the knowledge and documented competency to interpret and implement the written order.

4. Written policies and procedures regarding the agency's provision of intravenous therapy must include, but are not limited to, addressing initiation, medication administration, monitoring, and discontinuation. Responsibilities of the licensed nurse must be clearly delineated in written policies and procedures.

5. A registered nurse must be available 24 hours a day.

6. The client and caregiver must be assessed for the ability to safely administer the prescribed intravenous therapy as per agency written criteria.

7. If the client or caregiver is willing and able to safely administer the prescribed intravenous therapy, the agency must offer to teach the client or caregiver such administration. The teaching process is based on the client and caregiver needs and may include written instructions, verbal explanations, demonstrations, evaluation and documentation of competency, proficiency in performing intravenous therapy, scope of physical activities, and safe disposal of equipment.

8. Actions must be implemented prior to and during all intravenous therapy to minimize the risk of anaphylaxis or other adverse reactions as stated in the agency's written policy.

9. An ongoing assessment of client and caregiver compliance in performing intravenous therapy-related procedures must be done at periodic intervals.

10. Care coordination must be provided in order to assure continuity of care.

11. The client and caregiver must be provided with 24-hour access to appropriate health care professionals employed by or having a contract with the agency.

SUBCHAPTER E
DIVISION 1
§97.501 ~ SURVEY FREQUENCY

(a) At a minimum, DADS:

1. conducts an initial survey after an agency has notified DADS of its readiness (refer to §97.521);

2. conducts a survey of the agency within 18 months after conducting an initial survey and conducts subsequent surveys at least every 36 months thereafter; and

3. conducts a survey to investigate a complaint alleging:
   (A) abuse, neglect, or exploitation of a client as described in §97.502;
   (B) a violation of this chapter or the statute in the provision of licensed home health services, licensed and certified home health services, hospice services, or personal assistance services; and
   (C) a violation of federal requirements in the provision of licensed and certified home health services or licensed and certified hospice services.

4. investigates a self-reported incident that includes allegations of abuse, neglect, or exploitation of a client as described in §97.502.

(b) DADS may conduct a survey for the renewal of a license or the issuance of a branch office or alternate delivery site license.
§97.502 ~ STATE AGENCY INVESTIGATIONS OF COMPLAINTS AND SELF-REPORTED INCIDENTS
(a) This section applies when an alleged victim of abuse, neglect, or exploitation is an agency client and the alleged perpetrator of the abuse, neglect, or exploitation is an agency employee, volunteer, or contractor.
(b) In this section, facility regulated by DADS means any of the following:
   (1) an inpatient unit and residential unit licensed to provide hospice services to clients admitted to or residing in these units;
   (2) a nursing facility;
   (3) an assisted living facility;
   (4) an adult day care facility;
   (5) an adult foster care facility; and
   (6) a licensed intermediate care facility serving persons with mental retardation and related conditions.
(c) The Department of Family and Protective Services investigates a complaint or self-reported incident alleging abuse, neglect, or exploitation when:
   (1) the client involved is elderly or disabled; and
   (2) the alleged act occurs outside of a facility regulated by DADS as described in subsection (b) of this section.
(d) DADS investigates a complaint or self-reported incident alleging abuse, neglect, or exploitation of a client if the alleged act occurs in a facility regulated by DADS as described in subsection (b) of this section. DADS’ investigation may include:
   (1) a visit to the facility;
   (2) an interview with the client, if appropriate; and
   (3) interviews with persons believed to have knowledge of the circumstances.
(e) DADS investigates a complaint or a self-reported incident alleging abuse, neglect, or exploitation of a child if the alleged act occurs outside of a facility regulated by DADS as described in subsection (b) of this section. DADS’ investigation may include:
   (1) an interview with the child after making a reasonable effort to inform each parent of the nature of the allegation and of the need to interview the child; and
   (2) interviews with persons believed to have knowledge of the circumstances.
(f) DADS may conduct an interview in private or may include any person DADS determines is necessary.

§97.503 ~ EXEMPTION FROM A SURVEY
Except for the investigation of complaints, an agency is exempt from additional surveys by DADS if the agency maintains accreditation status for the applicable services from JCAHO or CHAP.

§97.505 ~ NOTICE OF A SURVEY
DADS does not announce or give prior notice to an agency of a survey.

§97.507 ~ AGENCY COOPERATION WITH A SURVEY
(a) By applying for or holding a license, an agency consents to entry and survey by a DADS representative to verify compliance with the statute or this chapter.
(b) An agency must provide the surveyor access to all agency records required by DADS to be maintained by or on behalf of the agency.
(c) If a surveyor requests an agency record that is stored at a location other than the survey site, the agency must provide the record to the surveyor within eight working hours after the request.
(d) An agency must provide the surveyor with copies of agency records upon request.
(e) During a survey, agency staff must not:
   (1) make a false statement that a person knows or should know is false of a material fact about a matter under investigation by DADS;
   (2) willfully interfere with the work of a DADS representative;
   (3) willfully interfere with a DADS representative in preserving evidence of a violation; or
(4) refuse to allow a DADS representative to inspect a book, record, or file required to be maintained by or on behalf of an agency.

(f) An agency must provide a DADS representative with a reasonable workspace and a safe workspace, free from hazards, at which to conduct a survey at a parent office, branch office, or alternate delivery site.

(g) If there is a disagreement between the agency and a DADS representative, the program manager or designee in the designated survey office determines what is reasonable and safe. After consulting with the program manager or designee and obtaining the program manager's agreement, the DADS representative will notify the agency administrator or designee if the requirement in subsection (f) of this section is not met. Within two working hours of this notice the agency must:
   (1) provide a DADS representative with a different workspace at the agency that meets the requirement in subsection (f) of this section; or
   (2) correct the unmet requirement in such a way as to allow the representative to reasonably and safely conduct the survey.

(h) If an agency willfully refuses to comply with subsection (g) of this section, thereby interfering with the work of the DADS representative, the representative will terminate the survey and recommend enforcement action as described in subsection (i) of this section.

(i) DADS may assess an administrative penalty without an opportunity to correct for a violation of provisions in this section, or may take other enforcement action to deny, revoke, or suspend a license, if an agency does not cooperate with a survey.

§97.509 ~ SURVEY OF A BRANCH OFFICE, ALTERNATE DELIVERY SITE, AND SERVICES PROVIDED
(a) If an agency is applying for or renewing a branch office or alternate delivery site license, a survey covers all locations.

(b) If an agency is applying for a license to provide more than one category of service, a survey covers all provided services of the agency.

DIVISION 2

§97.521 ~ REQUIREMENTS FOR AN INITIAL SURVEY
(a) No later than six months after the effective date of an agency's initial license, an agency must:
   (1) admit and provide services to clients as described in subsection (b) of this section; and
   (2) except as provided in subsection (f) of this section, submit a written request for an initial licensure survey to the designated survey office as described in subsection (c) of this section.

(b) Before submitting a written request to DADS for an initial licensure survey, an agency must admit clients and provide services as described in this subsection. The categories of service on an initial license may include LHHS, LHHS with home dialysis designation, hospice services, and PAS.
   (1) When an initial license includes only one category of service, an agency must admit and provide services to at least one client.
   (2) When an initial license includes the LHHS and the PAS categories, an agency must admit and provide LHHS to at least one client.
   (3) When an initial license includes the LHHS and the LHHS with home dialysis designation categories, with or without the PAS category, an agency must admit and provide LHHS with home dialysis designation to at least one client.
   (4) When an initial license includes the hospice services and the PAS categories, an agency must admit and provide hospice services to at least one client.
   (5) When an initial license includes the LHHS and the hospice services categories, with or without the PAS category, an agency must admit and provide LHHS services to at least one client and admit and provide hospice services to at least one client.
   (6) When an initial license includes the LHHS, the LHHS with home dialysis designation, and the hospice services categories, with or without the PAS category, an agency must admit and provide LHHS with home dialysis designation to at least one client. The agency must also admit and provide hospice services to at least one client.
(c) The agency’s written request for an initial survey must be submitted to the designated survey office using DADS Form 2020 Notification of Readiness for Initial Survey. The written request must include the name, date of admission, and the category of service provided to each client admitted for services to demonstrate that the agency has admitted clients and provided services as described in subsection (b) of this section.

(d) An agency must have the following information available and ready for review by a surveyor upon the surveyor’s arrival at the agency:

(1) a list of clients who are receiving services or who have received services from the agency for each category of service licensed. The list must comply with the requirements of §97.293;

(2) the client records for each client admitted during the licensing period before the initial survey;

(3) all agency policies as required by this chapter; and

(4) all personnel records of agency employees.

(e) DADS may propose to deny an application to renew, or revoke or suspend, an initial license for the reasons specified in §97.15(c).

(f) An agency is not required to request an initial survey in accordance with subsection (a)(2) of this section if the agency is exempt from the survey as specified in §97.503. To demonstrate that it is exempt, the agency must send the accreditation documentation from JCAHO or CHAP to the DADS designated survey office no later than six months after the effective date of its license.

(g) If an agency receives written notice of accreditation from JCAHO or CHAP after the agency submits a written request to DADS for an initial licensure survey, the agency may demonstrate that it is exempt from the survey by sending the accreditation documentation to the DADS designated survey office before DADS arrives at the agency to conduct an initial survey.

§97.523 ~ PERSONNEL REQUIREMENTS FOR A SURVEY

(a) For an initial survey, the administrator or alternate administrator must be present at the entrance conference, available in person or by telephone during the survey, and present in person at the exit conference.

(b) For a survey other than an initial survey, the administrator or alternate administrator must be available in person or by telephone during the entrance conference and the survey, and must be present in person at the exit conference.

(c) The supervising nurse or alternate supervising nurse must be available in person or by telephone, if necessary, to provide information unique to the duties and functions of the position during the survey.

(d) If a required individual is unavailable during the survey process and is not at the agency when the surveyor arrives, the surveyor makes reasonable attempts to contact the individual.

(e) If a surveyor arrives during regular business hours and the agency is closed, an administrator, alternate administrator, or a designated agency representative must provide the surveyor entry to the agency within two hours after the surveyor's arrival at the agency. The administrator must designate in writing the agency representatives who may grant entry to a surveyor. The agency must comply with notice requirements described in §97.210.

(f) If the surveyor is unable to contact a required individual or the agency fails to comply with subsection (e) of this section, the surveyor may recommend enforcement action against the agency.

(g) If compliance with this section would cause an interruption in client care being provided by the administrator, the alternate administrator, the supervising nurse, or the alternate supervising nurse, the administrator must contact its backup service provider to ensure continued client care.

§97.525 ~ SURVEY PROCEDURES

(a) Before beginning a survey, a surveyor holds an entrance conference, as specified in §97.523, to explain the purpose of the survey and the survey process and provides an opportunity to ask questions.
(b) During a survey, a surveyor:

1. conducts at least three home visits to determine an agency's compliance with licensing requirements;
2. reviews any agency records that the surveyor believes are necessary to determine an agency's compliance with licensing requirements; and
3. evaluates an agency's compliance with each standard.
   A. An agency accredited by CHAP or JCAHO must have the documentation of accreditation available at the time of a survey.
   B. DADS keeps agency records confidential, except as allowed by HSC §142.009(d).
   C. A surveyor may remove original agency records from an agency only with the consent of the agency as provided in HSC §142.009(e).

§97.527 ~ POST-SURVEY PROCEDURES

(a) After a survey is completed, the surveyor holds an exit conference with the administrator or alternate administrator to inform the agency of the preliminary findings.

(b) An agency may make an audio recording of the exit conference only if the agency:

1. records two tapes simultaneously;
2. allows the surveyor to review the tapes; and
3. gives the surveyor the tape of the surveyor's choice before leaving the agency.

(c) An agency may make a video recording of the exit conference only if the surveyor agrees to allow it and if the agency:

1. records two tapes simultaneously;
2. allows the surveyor to review the tapes; and
3. gives the surveyor the tape of the surveyor's choice before leaving the agency.

(d) An agency may submit additional written documentation and facts after the exit conference only if the agency describes the additional documentation and facts to the surveyor during the exit conference.

1. The agency must submit the additional written documentation and facts to the designated survey office within two working days after the end of the exit conference.
2. If an agency properly submits additional written documentation, the surveyor may add the documentation to the record of the survey.

(e) If DADS identifies additional violations or deficiencies after the exit conference, DADS holds an additional face-to-face exit conference with the agency regarding the additional violations or deficiencies.

(f) DADS provides official written notification of the survey findings to the agency within 10 working days after the exit conference.

(g) The official written notification of the survey findings includes a statement of violations and instructions for submitting an acceptable plan of correction, and provides an opportunity for an IRoD.

1. If the official written notification of the survey findings declares that an agency is in violation of the statute or this chapter, an agency must follow DADS instructions included with the statement of violations for submitting an acceptable plan of correction.
2. An acceptable plan of correction includes the corrective measures and time frame with which the agency must comply to ensure correction of a violation. If an agency fails to correct each violation by the date on the plan of correction, DADS may take enforcement action against the agency. An agency must correct a violation in accordance with the following time frames:
   A. A Severity Level B violation that results in serious harm to or death of a client or constitutes a serious threat to the health or safety of a client must be addressed upon receipt of the official written notice of the violations and corrected within two days.
   B. A Severity Level B violation that substantially limits the agency's capacity to provide care must be corrected within seven days after receipt of the official written notice of the violations.
   C. A Severity Level A violation that has or had minor or no health or safety significance must be corrected within 20 days after receipt of the official written notice of the violations.
(D) A violation that is not designated as Severity Level A or Severity Level B must be corrected within 60 days after the date the violation was cited.

(3) An agency must submit an acceptable plan of correction for each violation or deficiency no later than 10 days after its receipt of the official written notification of the survey findings.

(4) If DADS finds the plan of correction unacceptable, DADS gives the agency written notice and provides the agency one additional opportunity to submit an acceptable plan of correction. An agency must submit a revised plan of correction no later than 30 days after the agency's receipt of DADS written notice of an unacceptable plan of correction.

(h) An acceptable plan of correction does not preclude DADS from taking enforcement action against an agency.

(i) An agency must submit a plan of correction in response to an official written notification of survey findings that declares a violation or deficiency even if the agency disagrees with the survey findings.

(j) If an agency disagrees with the survey findings, the agency may request an IRoD and submit additional written information to refute a violation or deficiency to demonstrate compliance in an informal setting.

(1) An IRoD is available for:
   (A) a violation or deficiency cited during a visit;
   (B) a violation or deficiency that remains uncorrected from a previous visit and is re-cited with no change in findings, as long as the agency has not already had an IRoD for the violation or deficiency from the original visit; and
   (C) a violation or deficiency that remains uncorrected from a previous visit and is re-cited with new findings.

(2) To request an IRoD, an agency must:
   (A) mail or fax a complete and accurate IRoD request form to the address or fax number listed on the form, which must be postmarked or faxed within 10 days after the date of receipt of the official written notification of the survey findings;
   (B) mail or fax a rebuttal letter and supporting documentation to the address or fax number listed on the IRoD request form and ensure receipt by the DADS Survey and Certification Enforcement Unit within seven days after the postmark or fax date of the IRoD request form; and
   (C) mail or fax a copy of the IRoD request form, rebuttal letter, and supporting documentation to the designated survey office within the same time frames each is submitted to the DADS Survey and Certification Enforcement Unit.

(3) An agency may not submit information after the deadlines established in paragraph (2)(A) and (B) of this subsection unless DADS requests additional information. The agency's response to DADS request for information must be received within three working days after the request is made.

(4) An agency waives its right to an IRoD if the agency fails to submit the required information to the DADS Survey and Certification Enforcement Unit within the required time frames.

(5) An agency must present sufficient information to the DADS Survey and Certification Enforcement Unit to support the agency's desired IRoD outcome.

(6) The rebuttal letter and supporting documentation must include:
   (A) the disputed deficiencies or violations;
   (B) the reason the deficiencies or violations are disputed;
   (C) the desired outcome for each disputed deficiency or violation; and
   (D) attachments from client records, applicable policies and procedures, or other supporting documentation or information that directly demonstrates that the deficiency or violation should not have been cited.

(7) The written decision issued by DADS after the completion of its review is final.
SUBCHAPTER F
§97.601 ~ ENFORCEMENT ACTIONS

(a) Enforcement actions. DADS may take the following enforcement actions against an agency:

   (1) license suspension;
   (2) immediate license suspension;
   (3) license revocation;
   (4) immediate license revocation;
   (5) administrative penalties; and
   (6) denial of license application.

(b) Denial of license application. DADS may deny a license application for the reasons set out in §97.21.

(c) Suspension or revocation.

   (1) DADS may suspend or revoke an agency's license if the license holder, the controlling person,
       the affiliate, the administrator, or the alternate administrator:

       (A) fails to comply with this chapter;
       (B) fails to comply with the statute; or
       (C) violates Occupations Code, §102.001 and §102.006.

   (2) DADS may suspend or revoke an agency's license to provide licensed and certified home health
       services if the agency fails to maintain its certification qualifying the agency as a certified agency,
       as referenced in HSC §142.011(c).

(d) Administrative penalties.

   (1) DADS may assess an administrative penalty against an agency in accordance with §97.602.
   (2) DADS may consider the assessment of past administrative penalties when considering another
       enforcement action against an agency.

(e) Immediate licensure suspension or revocation. DADS may immediately suspend or revoke an
    agency's license when the health and safety of persons are threatened.

   (1) If DADS issues an order for immediate suspension or revocation of the agency's license, DADS
       provides immediate notice to the controlling person, administrator, or alternate administrator of
       the agency by fax and either by certified mail with return receipt requested or hand-delivery. The
       notice includes:

       (A) the action taken;
       (B) legal grounds for the action;
       (C) the procedure governing appeal of the action; and
       (D) the effective date of the order.

   (2) An order for immediate suspension or revocation goes into effect immediately.

   (3) An agency is entitled to a formal administrative hearing not later than seven days after the
       effective date of the order for immediate suspension or revocation.

   (4) If an agency requests a formal administrative hearing, the hearing is held in accordance with the
       Government Code, Chapter 2001, and with the formal hearing procedures in 1 TAC Chapter 357
       Subchapter I and 40 TAC Chapter 91.

(f) Opportunity to show compliance.

   (1) Before revocation or suspension of an agency's license or denial of an application for the renewal
       of an agency's license, DADS gives the license holder:

       (A) a notice by personal service or by registered or certified mail of the facts or conduct alleged to
           warrant the proposed action, with a copy sent to the agency; and

       (B) an opportunity to show compliance with all requirements of law for the retention of the license
           by sending DADS Regulatory Services office a written request. The request must:

           (i) be postmarked within 10 days after the date of DADS notice and be received in DADS
               Regulatory Services office within 10 days after the date of the postmark; and

           (ii) contain specific documentation refuting DADS allegations.

   (2) DADS limits its review to the documentation submitted by the license holder and information
       DADS used as the basis for its proposed action. An agency may not attend DADS meeting to
review the opportunity to show compliance. DADS gives a license holder a written affirmation or reversal of the proposed action.

(3) After an opportunity to show compliance, DADS sends a license holder a written notice that:
   (A) informs the license holder of DADS decision; and
   (B) provides the agency with an opportunity to appeal DADS decision through a formal hearing process.

(g) Notice of denial of application for license or renewal of a license, suspension or revocation of license. DADS sends an applicant or license holder notice by fax and either by certified mail with return receipt requested or hand-delivery of DADS denial of an application for an initial license or renewal of a license, suspension of a license or revocation of a license.

(h) Formal appeal. An applicant or license holder has the right to make a formal appeal after receipt of DADS notification of denial of an application for an initial license or renewal of a license and suspension or revocation of a license.

   (1) An agency must request a formal administrative hearing within 20 days of receipt of DADS notice of denial of an application for an initial license or renewal of a license, suspension of a license or revocation of a license. To make a formal appeal, the applicant or agency must comply with the formal hearing procedures in 1 TAC Chapter 357 Subchapter I and 40 TAC Chapter 91.

   (2) DADS presumes receipt of DADS notice to occur on the tenth day after the notice is mailed to the last known address unless another date is reflected on the return receipt.

   (3) If an agency does not meet the deadline for requesting a formal hearing, the agency has lost its opportunity for a formal hearing, and DADS takes the proposed action.

   (4) A formal administrative hearing is held in accordance with Government Code, Chapter 2001, and the formal hearing procedures in 1 TAC Chapter 357 Subchapter I and 40 TAC Chapter 91.

   (5) Except for the denial of an application for an initial license, if an agency appeals, the license remains valid until all appeals are final, unless the license expires without a timely application for renewal submitted to DADS. The agency must continue to submit a renewal application in accordance with §97.17 until the action to revoke, suspend, or deny renewal of the license is completed. However, DADS does not renew the license until it determines the reason for the proposed action no longer exists.

   (6) If an agency appeals, the enforcement action will take effect when all appeals are final and the proposed enforcement action is upheld. If the agency wins the appeal, the proposed action does not happen.

   (7) If DADS suspends a license, the suspension remains in effect until DADS determines that the reason for suspension no longer exists. A suspension may last no longer than the term of the license. DADS conducts a survey of the agency before making a determination to recommend cancellation of a suspension.

   (8) If DADS revokes or does not renew a license and one year has passed following the effective date of revocation or denial of licensure renewal, a person may reapply for a license by complying with the requirements and procedures in §97.13. DADS does not issue a license if the reason for revocation or nonrenewal continues to exist.

(i) Agency dissolution. Upon suspension, revocation, or nonrenewal of a license, the license holder must:
   (1) return the original license to DADS; and
   (2) implement its written plan required in §97.291.

§97.602 ~ Administrative Penalties

(a) Assessing penalties. DADS may assess an administrative penalty against a person who violates:
   (1) the statute;
   (2) a provision in this chapter for which a penalty may be assessed; or
   (3) Occupations Code, §102.001 or §102.006, if related to the provision of home health, hospice, or personal assistance services.
(b) Criteria for assessing penalties. DADS assesses administrative penalties in accordance with the schedule of appropriate and graduated penalties established in this section.

1. The schedule of appropriate and graduated penalties for each violation is based on the following criteria:
   - the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation and the hazard of the violation to the health or safety of clients;
   - the history of previous violations by a person or a controlling person with respect to that person;
   - whether the affected agency identified the violation as part of its internal quality assurance process and made a good faith, substantial effort to correct the violation in a timely manner;
   - the amount necessary to deter future violations;
   - efforts made to correct the violation; and
   - any other matters that justice may require.

2. In determining which violation warrants a penalty, DADS considers:
   - the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation and the hazard of the violation to the health or safety of clients; and
   - whether the affected agency identified the violation as part of its internal quality assurance program and made a good faith, substantial effort to correct the violation in a timely manner.

(c) Opportunity to correct. Except as provided in subsections (e) and (f) of this section, DADS provides an agency with an opportunity to correct a violation in accordance with the time frames established in §97.527(g)(2) before assessing an administrative penalty if a plan of correction has been implemented.

(d) Minor violations.

1. DADS may not assess an administrative penalty for a minor violation unless the violation is of a continuing nature or is not corrected in accordance with an accepted plan of correction.

2. DADS may assess an administrative penalty for a subsequent occurrence of a minor violation when cited within three years from the date the agency first received written notice of the violation.

3. DADS does not assess an administrative penalty for a subsequent occurrence of a minor violation when cited more than three years from the date the agency first received written notice of the violation.

(e) No opportunity to correct. DADS may assess an administrative penalty without providing an agency with an opportunity to correct a violation if DADS determines that the violation:

1. results in serious harm to or death of a client;
2. constitutes a serious threat to the health or safety of a client;
3. substantially limits the agency's capacity to provide care;
4. involves the provisions of HRC Chapter 102, Rights of the Elderly;
5. is a violation in which a person:
   - makes a false statement, that the person knows or should know is false of a material fact: (i) on an application for issuance or renewal of a license or in an attachment to the application; or (ii) with respect to a matter under investigation by DADS;
   - refuses to allow a representative of DADS to inspect a book, record, or file required to be maintained by an agency;
   - willfully interferes with the work of a representative of DADS or the enforcement of this chapter;
   - willfully interferes with a representative of DADS preserving evidence of a violation of this chapter or a rule, standard, or order adopted or license issued under this chapter;
   - fails to pay a penalty assessed by DADS under this chapter not later than the 10th day after the date the assessment of the penalty becomes final; or
   - fails to submit:
(i) a plan of correction not later than the 10th day after the date the person receives a statement of licensing violations; or
(ii) an acceptable plan of correction not later than the 30th day after the date the person receives notification from DADS that the previously submitted plan of correction is not acceptable.

(f) Violations relating to Advance Directives. As provided in HSC §142.0145, DADS assesses an administrative penalty of $500 for a violation of §97.283 without providing an agency with an opportunity to correct the violation.

(g) Penalty calculation and assessment.
(1) Each day that a violation occurs before the date on which the person receives written notice of the violation is considered one violation.
(2) Each day that a violation occurs after the date on which an agency receives written notice of the violation constitutes a separate violation.

(h) Schedule of appropriate and graduated penalties.
(1) If two or more rules listed in paragraphs (2) and (3) of this subsection relate to the same or similar matter, one administrative penalty may be assessed at the higher severity level violation.
(2) Severity Level A violations. (refer to the table on pgs 84-88)
   (A) The penalty range for a Severity Level A violation is $100 - $250 per violation.
   (B) A Severity Level A violation is a violation that has or has had minor or no client health or safety significance.
   (C) DADS assesses a penalty for a Severity Level A violation only if the violation is of a continuing nature or was not corrected in accordance with an accepted plan of correction.
   (D) DADS may assess a separate Severity Level A administrative penalty for each of the rules listed in the following table.
(3) Severity Level B violations. (refer to the table on pgs 89-94)
   (A) The penalty range for a Severity Level B violation is $500 - $1,000 per violation.
   (B) A Severity Level B violation is a violation that:
      (i) results in serious harm to or death of a client;
      (ii) constitutes an actual serious threat to the health or safety of a client; or
      (iii) substantially limits the agency's capacity to provide care.
   (C) The penalty for a Severity Level B violation that:
      (i) results in serious harm to or death of a client is $1,000;
      (ii) constitutes an actual serious threat to the health or safety of a client is $500 - $1,000; and
      (iii) substantially limits the agency's capacity to provide care is $500 - $750.
   (D) As provided in subsection (e) of this section, a Severity Level B violation is a violation for which DADS may assess an administrative penalty without providing an agency with an opportunity to correct the violation.
   (E) DADS may assess a separate Severity Level B administrative penalty for each of the rules listed in the following table.
(i) Violations for which DADS may assess an administrative penalty of $500.
   (1) DADS may assess an administrative penalty of $500 for each of the violations listed in subsection (e)(4) and (5) of this section, without providing an agency with an opportunity to correct the violation.
   (2) A separate penalty may be assessed for each of these violations.

(j) Proposal of administrative penalties.
(1) If DADS assesses an administrative penalty, DADS provides a written notice of violation letter to an agency. The notice includes:
   (A) a brief summary of the violation;
   (B) the amount of the proposed penalty; and
(C) a statement of the agency's right to a formal administrative hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(2) An agency may accept DADS determination not later than 20 days after the date on which the agency receives the notice of violation letter, including the proposed penalty, or may make a written request for a formal administrative hearing on the determination.

(A) If an agency notified of a violation accepts DADS determination, the DADS commissioner or the DADS commissioner's designee issues an order approving the determination and ordering that the agency pay the proposed penalty.

(B) If an agency notified of a violation does not accept DADS determination, the agency must submit to the Health and Human Services Commission a written request for a formal administrative hearing on the determination and must not pay the proposed penalty. Remittance of the penalty to DADS is deemed acceptance by the agency of DADS determination, is final, and waives the agency's right to a formal administrative hearing.

(C) If an agency notified of a violation fails to respond to the notice of violation letter within the required time frame, the DADS commissioner or the DADS commissioner's designee issues an order approving the determination and ordering that the agency pay the proposed penalty.

(D) If an agency requests a formal administrative hearing, the hearing is held in accordance with the statute, §142.0172, §142.0173, and the formal hearing procedures in 1 TAC Chapter 357 Subchapter I and 40 TAC Chapter 91.

§97.603 ~ COURT ACTION
(a) If a person operates an agency without a license issued under this chapter, the person is liable for a civil penalty of not less than $1,000 or more than $2,500 for each day of violation.

(b) If a person violates the licensing requirements of the statute, DADS may petition the district court to restrain the person from continuing the violation.

§97.604 ~ SURRENDER OR EXPIRATION OF A LICENSE
(a) After a survey in which a surveyor cited deficiencies, an agency may surrender its license or allow its license to expire to avoid enforcement action by DADS.

(b) If an agency surrenders its license before the expiration date, the agency must return its original license and provide the following information to DADS:

1. the effective date of closure;
2. the location of client records;
3. the name and address of the client record custodian;
4. a statement signed and dated by the license holder agreeing to the surrender of the license; and
5. the disposition of active clients at the time of closure.

(c) If an agency surrenders its license or allows its license to expire, DADS denies an application for license by the agency, its license holder, and its affiliate for one year after the date of the surrender or expiration.

SUBCHAPTER G
§97.701 ~ HOME HEALTH AIDES
(a) A home health aide may be used by an agency providing licensed home health services if the aide meets one of the following requirements:

1. a minimum of one year full-time experience in direct client care in an institutional setting (hospital or nursing facility);
2. one year full-time experience within the last five years in direct client care in an agency setting;
3. satisfactorily completed a training and competency evaluation program that complies with the requirements of this section;
4. satisfactorily completed a competency evaluation program that complies with the requirements of this section;
(5) submitted to the agency documentation from the director of programs or the dean of a school of nursing that states that the individual is a nursing student who has demonstrated competency in providing basic nursing skills in accordance with the school's curriculum; or
(6) be on the Texas Department of Human Services' (DHS's) nurse aide registry with no finding against the aide relating to client abuse or neglect or misappropriation of client property.

(b) A home health aide must have provided home health services within the previous 24 months to qualify under subsection (a)(3) or (4) of this section.

(c) Assignment, delegation, and supervision of services provided by home health aides must be performed in accordance with rules in this chapter governing the agency's license category.

(d) The training portion of a training and competency evaluation program for home health aides must be conducted by or under the general supervision of an RN who possesses a minimum of two years of nursing experience, at least one year of which must be in the provision of home health care. The training program may contain other aspects of learning, but must contain the following:

1. a minimum of 75 hours as follows:
   (A) an appropriate number of hours of classroom instruction; and
   (B) a minimum of 16 hours of clinical experience which will include in-home training and must be conducted in a home, a hospital, a nursing home, or a laboratory;
2. completion of at least 16 hours of classroom training before a home health aide begins clinical experience working directly with clients under the supervision of qualified instructors;
3. if LVN instructors are used for the training portion of the program, the following qualifications and supervisory requirements apply:
   (A) an LVN may provide the home health aide classroom training under the supervision of an RN who has two years of nursing experience, at least one year of which must be in the provision of home health care;
   (B) LVNs, as well as RNs, may supervise home health aide candidates in the course of the clinical experience; and
   (C) an RN must maintain overall responsibility for the training and supervision of all home health aide training students; and
4. an assessment that the student knows how to read and write English and carry out directions.

(e) The classroom instruction and clinical experience content of the training portion of a training and competency evaluation program must include, but is not limited to:

1. communication skills;
2. observation, reporting, and documentation of a client's status and the care or service furnished;
3. reading and recording temperature, pulse, and respiration;
4. basic infection control procedures and instruction on universal precautions;
5. basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;
6. maintenance of a clean, safe, and healthy environment;
7. recognizing emergencies and knowledge of emergency procedures;
8. the physical, emotional, and developmental needs of and ways to work with the populations served by the agency including the need for respect for the client and his or her privacy and property;
9. appropriate and safe techniques in personal hygiene and grooming that include:
   (A) bed bath;
   (B) sponge, tub, or shower bath;
   (C) shampoo, sink, tub, or bed;
   (D) nail and skin care;
   (E) oral hygiene; and
   (F) toileting and elimination;
10. safe transfer techniques and ambulation;
11. normal range of motion and positioning;
(12) adequate nutrition and fluid intake;
(13) any other task the agency may choose to have the home health aide perform in accordance with §97.298; and
(14) the rights of the elderly.

(f) This section addresses the requirements for the competency evaluation program or the competency evaluation portion of a training and competency evaluation program.

(1) The competency evaluation must be performed by an RN.
(2) The competency evaluation must address each of the subjects listed in subsection (e)(2) - (13) of this section.
(3) Each of the areas described in subsection (e)(3) and (9) - (11) of this section must be evaluated by observation of the home health aide's performance of the task with a client or person.
(4) Each of the areas described in subsection (e)(2), (4) - (8), (12), and (13) of this section may be evaluated through written examination, oral examination, or by observation of a home health aide with a client.
(5) A home health aide is not considered to have successfully completed a competency evaluation if the aide has an unsatisfactory rating in more than one of the areas described in subsection (e)(2) - (13) of this section.
(6) If an aide receives an unsatisfactory rating, the aide must not perform that task without direct supervision by an RN or LVN until the aide receives training in the task for which he or she was evaluated as unsatisfactory and successfully completes a subsequent competency evaluation with a satisfactory rating on the task.
(7) If an individual fails to complete the competency evaluation satisfactorily, the individual must be advised of the areas in which he or she is inadequate.

(g) If a person, who is not an agency licensed under this section, desires to implement a home health aide training and competency evaluation program or a competency evaluation program, the person must meet the requirements of this section in the same manner as set forth for an agency.
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<tbody>
<tr>
<td>§97.212</td>
<td>Prohibiting material alteration of a license.</td>
</tr>
<tr>
<td>§97.213(a)-(b) separate penalties</td>
<td>Agency relocation.</td>
</tr>
<tr>
<td>§97.214(a)-(b) separate penalties</td>
<td>Notification procedures for reporting a change in agency telephone number and agency operating hours.</td>
</tr>
<tr>
<td>§97.216(a)</td>
<td>Change in agency certification or accreditation status.</td>
</tr>
<tr>
<td>§97.217(b)(1)-(2) separate penalties</td>
<td>Procedures for notifying DADS of a voluntary suspension of operations.</td>
</tr>
<tr>
<td>§97.218(a)-(b) separate penalties</td>
<td>Notice of agency organizational changes and submitting criminal history check consent forms.</td>
</tr>
<tr>
<td>§97.219</td>
<td>Procedure for adding or deleting a category of service to the agency's license.</td>
</tr>
<tr>
<td>§97.220(a)(2)</td>
<td>Providing services only within an agency's licensed service area.</td>
</tr>
<tr>
<td>§97.220(c)</td>
<td>Providing a written notification of an expansion of an agency's licensed service area.</td>
</tr>
<tr>
<td>§97.220(d)</td>
<td>Providing written notification of a reduction of an agency's licensed service area.</td>
</tr>
<tr>
<td>§97.242(a)-(b) separate penalties</td>
<td>Preparing and maintaining a current written description of the agency's organizational structure.</td>
</tr>
<tr>
<td>§97.243(b)(1)(A)-(B) and (D)-(G) separate penalties</td>
<td>Responsibilities of the administrator.</td>
</tr>
<tr>
<td>§97.243(b)(3)</td>
<td>Requirement that the administrator designate in writing an agency employee who must provide DADS surveyors entry to the agency.</td>
</tr>
<tr>
<td>§97.243(d)</td>
<td>Adoption of a written policy for the supervision of branch offices or alternate delivery sites, if established.</td>
</tr>
<tr>
<td>§97.244(b)(1)-(5) separate penalties</td>
<td>Conditions of the agency administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.245(a)-(b)(1)-(10) separate penalties</td>
<td>Adoption and enforcement of written policies governing all personnel staffed by the agency.</td>
</tr>
<tr>
<td>§97.246(a)(1)-(6)(A)-(B) and (b) separate penalties</td>
<td>An agency's personnel records and content of such records.</td>
</tr>
<tr>
<td>§97.247(a)(4) and (b)(4) separate penalties</td>
<td>Providing unlicensed employees and volunteers with written information about the employee misconduct registry.</td>
</tr>
<tr>
<td>§97.247(c)</td>
<td>Documentation of compliance with verifying the employability and use of unlicensed applicants, employees, and volunteers.</td>
</tr>
<tr>
<td>§97.248(a)-(b)(1)-(4) separate penalties</td>
<td>The use of volunteers in an agency.</td>
</tr>
<tr>
<td>§97.249(b)</td>
<td>Adoption of a written policy for the reporting of alleged acts of abuse, neglect, and exploitation of clients.</td>
</tr>
<tr>
<td>§97.250(a)</td>
<td>Adoption of a written policy covering procedures for investigating known and alleged acts of abuse, neglect, and exploitation and other complaints.</td>
</tr>
</tbody>
</table>
### SEVERITY LEVEL A VIOLATIONS

$100 - $250 per violation  
§97.602(h)(2)(D)

<table>
<thead>
<tr>
<th>Rule</th>
<th>Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>§97.250(e)</td>
<td>Prohibiting an agency from retaliating against a person for filing a complaint, presenting a grievance, or providing, in good faith, information about the services provided by the agency.</td>
</tr>
<tr>
<td>§97.251</td>
<td>Adoption of a written policy for ensuring that all professional disciplines comply with their respective professional practice acts or title acts for reporting and peer review.</td>
</tr>
<tr>
<td>§97.253</td>
<td>Adoption of a written policy describing whether an agency will conduct drug testing of employees that describes the method and provides a copy of the policy.</td>
</tr>
<tr>
<td>§97.254</td>
<td>Adoption of a written policy for ensuring that the agency submits accurate billings and insurance claims.</td>
</tr>
<tr>
<td>§97.255</td>
<td>Adoption of a written policy for prohibition of illegal remuneration for securing or soliciting clients or patronage.</td>
</tr>
<tr>
<td>§97.256</td>
<td>Development and documentation of a written emergency preparedness and response plan.</td>
</tr>
<tr>
<td>§97.256(1)(A)-(M) separate penalties</td>
<td>Developing, maintaining and implementing a written emergency preparedness and response plan.</td>
</tr>
<tr>
<td>§97.259(g)</td>
<td>Prohibiting use of the presurvey conference to meet initial training requirements for a first-time administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.260(d)</td>
<td>Prohibiting use of the pre-survey conference to meeting continuing education requirements for an administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.281(1)-(16) separate penalties</td>
<td>Adoption of a written policy that specifies the agency’s client care practices.</td>
</tr>
<tr>
<td>§97.282(a)-(b), (d)-(f)(1)-(8), and (g)-(h) separate penalties</td>
<td>Adoption of a written policy governing client conduct and responsibility and client rights.</td>
</tr>
<tr>
<td>§97.284</td>
<td>Adoption of a written policy for complying with the Clinical Laboratory Improvement Amendments of 1988, 42 USC, §263a, Certification of Laboratories (CLIA 1988).</td>
</tr>
<tr>
<td>§97.285</td>
<td>Adoption of written policies addressing infection control.</td>
</tr>
<tr>
<td>§97.285(1)(A)-(C) and (2) separate penalties</td>
<td>Adoption and compliance with a written policy that addresses infection control.</td>
</tr>
<tr>
<td>§97.286(a)</td>
<td>Adoption of a written policy for safe handling and disposal of biohazardous waste and materials, if applicable.</td>
</tr>
<tr>
<td>§97.288(a)</td>
<td>Adoption of a written policy that all service providers involved in the care of a client effectively coordinate the client's care.</td>
</tr>
<tr>
<td>§97.289(c)(2)</td>
<td>Providing written information about the employee misconduct registry to an unlicensed person providing services under arrangement.</td>
</tr>
<tr>
<td>§97.289(e)(1)-(3) separate penalties</td>
<td>Documentation of personnel qualifications and for unlicensed staff that provide services under arrangement.</td>
</tr>
<tr>
<td>§97.290(a)</td>
<td>Adoption of a written policy for ensuring that backup services are available when an agency employee or contractor is not available to deliver the services.</td>
</tr>
<tr>
<td>97.290(a)(1)-(2)</td>
<td>Documentation that a client’s designee agreed to provide backup services.</td>
</tr>
<tr>
<td>97.290(a)(3)</td>
<td>Not coercing a client to accept backup services.</td>
</tr>
<tr>
<td>§97.290(b)</td>
<td>Adoption of a written policy for ensuring that clients are educated in how to access care from the agency or another health care provider after regular business hours.</td>
</tr>
<tr>
<td>§97.291</td>
<td>Adoption of a written policy for an agency’s written contingency plan.</td>
</tr>
</tbody>
</table>
**SEVERITY LEVEL A VIOLATIONS**

$100 - $250 per violation

§97.602(h)(2)(D)

<table>
<thead>
<tr>
<th>Rule</th>
<th>Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>§97.292(a)</td>
<td>Providing a client or a client's family with a written agreement for services and ensuring appropriate content of the agreement.</td>
</tr>
<tr>
<td>97.292(b)</td>
<td>Obtaining acknowledgment that the client received an appropriate written agreement for services and ensuring that the acknowledgment is in the client's record.</td>
</tr>
<tr>
<td>§97.293</td>
<td>Maintaining a current list of clients for each category of service licensed.</td>
</tr>
<tr>
<td>§97.294</td>
<td>Adoption of a written policy for establishing a time frame for the initiation of care or services.</td>
</tr>
<tr>
<td>§97.295(c), (d), and (f) separate penalties</td>
<td>Delivery of written notice and documentation requirements pertaining to an agency's transfer or discharge of a client.</td>
</tr>
<tr>
<td>§97.296(a)</td>
<td>Adoption of a written policy that states whether physician delegation will be honored by the agency.</td>
</tr>
<tr>
<td>97.296(b)</td>
<td>Information the agency must receive to accept physician delegation.</td>
</tr>
<tr>
<td>§97.297</td>
<td>Adoption of a written policy describing protocols and procedures agency staff must follow when receiving physician orders, if applicable.</td>
</tr>
<tr>
<td>§97.297(2)</td>
<td>Physician orders received by facsimile.</td>
</tr>
<tr>
<td>§97.298</td>
<td>Adoption of a written policy for ensuring compliance with rules adopted by the Texas Board of Nursing in 22 TAC Chapter 224 (Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments) and 22 TAC Chapter 225 (RN Delegation to Unlicensed Personnel and Tasks Not Requiring Delegation in Independent Living Environments for Clients with Stable and Predictable Conditions).</td>
</tr>
<tr>
<td>§97.299</td>
<td>Adoption of a written policy for ensuring compliance with rules of the Texas Board of Nursing adopted at 22 TAC Chapters 211-226 (Nursing Continuing Education, Licensure, and Practice in the State of Texas).</td>
</tr>
<tr>
<td>§97.300(b)</td>
<td>Adoption of a written policy for maintaining a current medication list and a current medication administration record.</td>
</tr>
<tr>
<td>§97.300(b)(2)(A)-(B) separate penalties</td>
<td>The administration of medication.</td>
</tr>
<tr>
<td>§97.301(a)(1)-(9)(A)-(P) separate penalties</td>
<td>Requirements for maintaining an agency's client records.</td>
</tr>
<tr>
<td>§97.301(b)(1)-(3) separate penalties</td>
<td>Adoption and enforcement of a written policy for retention of records.</td>
</tr>
<tr>
<td>§97.302</td>
<td>Adoption of a written policy for pronouncement of death if that function is carried out by an agency registered nurse.</td>
</tr>
<tr>
<td>§97.321(a)</td>
<td>Branch office compliance with the regulations of its parent agency.</td>
</tr>
<tr>
<td>§97.321(c)(1)</td>
<td>Providing services only within a branch office licensed service area.</td>
</tr>
<tr>
<td>§97.321(c)(3)</td>
<td>Providing a written notification of an expansion of a branch office service area.</td>
</tr>
<tr>
<td>§97.321(c)(4)</td>
<td>Providing written notification of a reduction of a branch office licensed service area.</td>
</tr>
<tr>
<td>§97.321(d)(1)-(3) separate penalties</td>
<td>Requirements for branch offices.</td>
</tr>
<tr>
<td>§97.321(f)</td>
<td>Requirement prohibiting branch offices from providing services not offered by the parent agency.</td>
</tr>
<tr>
<td>Rule</td>
<td>Subject Matter</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
</tr>
<tr>
<td>§97.322(a)</td>
<td>Alternate delivery site compliance with hospice services standards.</td>
</tr>
<tr>
<td>§97.322(b)</td>
<td>An alternate delivery site's independent compliance with §97.403(c), (f)(1), (i), and §97.301.</td>
</tr>
<tr>
<td>§97.322(c)(1)</td>
<td>Providing services only within an alternate delivery site licensed service area.</td>
</tr>
<tr>
<td>§97.322(c)(3)</td>
<td>Providing a written notification of an expansion of an alternate delivery site service area.</td>
</tr>
<tr>
<td>§97.322(c)(4)</td>
<td>Providing written notification of a reduction of an alternate delivery site licensed service area.</td>
</tr>
<tr>
<td>§97.322(d)(1)-(3) separate penalties</td>
<td>Requirements for hospices and alternate delivery sites.</td>
</tr>
<tr>
<td>§97.401(f)</td>
<td>The use of home health aides.</td>
</tr>
<tr>
<td>§97.402(b)</td>
<td>Requirement for implementing a home health aide training and competency program.</td>
</tr>
<tr>
<td>§97.403(b)</td>
<td>Restriction on use of the word &quot;hospice&quot; in a title or description of a facility, organization, program, service provider, or services without a license.</td>
</tr>
<tr>
<td>§97.403(c)</td>
<td>Adoption of a written policy for the provision of hospice services.</td>
</tr>
<tr>
<td>§97.403(e)(3)</td>
<td>Designating which among multiple interdisciplinary teams is responsible for establishing the policies governing day-to-day hospice functions.</td>
</tr>
<tr>
<td>§97.403(f)(4)</td>
<td>Retaining responsibility for payment for services.</td>
</tr>
<tr>
<td>§97.403(j)</td>
<td>Requirement that reassessment of a client must not reduce core services.</td>
</tr>
<tr>
<td>§97.403(k)</td>
<td>Informing the client of the availability of short-term inpatient care.</td>
</tr>
<tr>
<td>§97.403(l)</td>
<td>Making and documenting efforts to arrange for visits of clergy and other members of spiritual and religious organizations.</td>
</tr>
<tr>
<td>§97.403(u)(4)</td>
<td>Specifying the persons authorized to administer medications in the</td>
</tr>
<tr>
<td>§97.403(w)(2)(A)-(G) separate penalties</td>
<td>Development and documentation of a written emergency preparedness and response plan for a freestanding hospice in the event of a disaster.</td>
</tr>
<tr>
<td>§97.403(w)(5)-(6) and (8) separate penalties</td>
<td>Physical plant requirements in a freestanding hospice that provides inpatient care.</td>
</tr>
<tr>
<td>§97.403(w)(11)(A)-(D) separate penalties</td>
<td>Providing and supervising meal service in a freestanding hospice that provides inpatient care.</td>
</tr>
<tr>
<td>§97.404(e)</td>
<td>Requirement that an agency develops operational policies that are considerate of the principles of individual and family choice and control, functional need, and accessible and flexible services.</td>
</tr>
<tr>
<td>§97.404(f)(1)-(3) separate penalties</td>
<td>Additional requirements for maintaining client records in an agency that provides personal assistance services.</td>
</tr>
<tr>
<td>§97.404(g)</td>
<td>Adoption of a written policy that addresses the supervision of agency personnel with input from the client or family on the frequency of supervision.</td>
</tr>
<tr>
<td>§97.404(g)(1)-(2) separate penalties</td>
<td>Conditions and qualifications for supervision of agency personnel delivering personal assistance services.</td>
</tr>
</tbody>
</table>
## SEVERITY LEVEL A VIOLATIONS

$100 - $250 per violation

§97.602(h)(2)(D)

<table>
<thead>
<tr>
<th>Rule</th>
<th>Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>§97.405(d)</td>
<td>Requirement for individual personnel files on all physicians.</td>
</tr>
<tr>
<td>§97.405(g)</td>
<td>A written transfer agreement with a local hospital for an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(h)</td>
<td>An agreement with a licensed end stage renal disease facility to provide backup outpatient dialysis services.</td>
</tr>
<tr>
<td>§97.405(j)</td>
<td>Ensuring that names of clients awaiting a donor transplant are entered in the recipient registry program.</td>
</tr>
<tr>
<td>§97.405(s)(1) and (4)-(7) separate penalties</td>
<td>Additional requirements for maintaining client records in an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(v)</td>
<td>Development of a written preventive maintenance program for home dialysis equipment.</td>
</tr>
<tr>
<td>§97.405(v)(1)(B)</td>
<td>Maintaining written evidence of preventive maintenance and equipment repairs.</td>
</tr>
<tr>
<td>§97.405(z)</td>
<td>Adoption of policies and procedures for medical emergencies and emergencies resulting from a disaster required of an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.406(1)</td>
<td>Adoption of a written policy for the provision of psychoactive treatments, if applicable.</td>
</tr>
<tr>
<td>§97.521(a)</td>
<td>Requirement for initiation of services for receiving an initial license.</td>
</tr>
<tr>
<td>§97.523(a)</td>
<td>Staff availability for the initial survey.</td>
</tr>
<tr>
<td>§97.523(b)</td>
<td>Staff availability for survey other than the initial survey.</td>
</tr>
<tr>
<td>§97.523(e)</td>
<td>Providing surveyor entry to the agency during regular business hours and within two hours of the surveyor's arrival at the agency.</td>
</tr>
<tr>
<td>97.525(c)</td>
<td>Having documentation of accreditation available at the time of a survey.</td>
</tr>
<tr>
<td>§97.527(b)</td>
<td>Providing surveyor with audio recording of the exit conference if made by the agency.</td>
</tr>
<tr>
<td>§97.527(c)</td>
<td>Providing surveyor with video recording of the exit conference if made by the agency.</td>
</tr>
<tr>
<td>§97.527(g)(1)-(2)(A)-(D)</td>
<td>Submitting an acceptable plan of correction and correcting a violation within the required time frame.</td>
</tr>
<tr>
<td>Rule</td>
<td>Subject Matter</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
</tr>
<tr>
<td>§97.11(d)</td>
<td>Requirement to have a separate license for each place of business.</td>
</tr>
<tr>
<td>§97.23</td>
<td>A license may not be sold or assigned to another person.</td>
</tr>
<tr>
<td>§97.220(b)</td>
<td>Maintaining adequate staff to provide services and supervise the provision of services within the service area.</td>
</tr>
<tr>
<td>§97.241(a), (c), and (d) separate penalties</td>
<td>Management responsibilities.</td>
</tr>
<tr>
<td>§97.243(a)(1)</td>
<td>Designating a qualified agency administrator.</td>
</tr>
<tr>
<td>§97.243(a)(2)</td>
<td>Designating a qualified agency alternate administrator.</td>
</tr>
<tr>
<td>§97.243(b)(1)(A)-(F) and (2)-(3) separate penalties</td>
<td>Responsibilities of an agency administrator.</td>
</tr>
<tr>
<td>§97.243(c)(1)</td>
<td>Requirement to directly employ or contract with a qualified individual to serve as the supervising nurse.</td>
</tr>
<tr>
<td>§97.243(c)(2)</td>
<td>Requirement to designate a qualified alternate supervising nurse.</td>
</tr>
<tr>
<td>§97.243(c)(2)(A) and (B) separate penalties</td>
<td>Supervisory responsibilities of the supervising nurse or alternate supervising nurse.</td>
</tr>
<tr>
<td>§97.243(c)(2)(B)</td>
<td>Allowing the supervising nurse to be the administrator if the supervising nurse meets the qualifications of the administrator.</td>
</tr>
<tr>
<td>§97.243(c)(3)</td>
<td>Requirements for the supervision of physical, occupational, speech, or respiratory therapy; medical social services; or nutritional counseling.</td>
</tr>
<tr>
<td>§97.243(d)</td>
<td>Enforcing a written policy for the supervision of branch offices or alternate delivery sites, if established.</td>
</tr>
<tr>
<td>§97.244(a)(1)</td>
<td>Qualifications of the agency administrator and alternate administrator for agencies licensed to provide licensed home health services, licensed and certified home health services or hospice services.</td>
</tr>
<tr>
<td>§97.244(a)(2)</td>
<td>Qualifications of the agency administrator and alternate administrator for agencies licensed to provide only personal assistance services.</td>
</tr>
<tr>
<td>§97.244(b)(1)-(5) separate penalties</td>
<td>Conditions of the agency administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.244(c)(1)</td>
<td>Qualifications of the supervising nurse and alternate supervising nurse for agencies without the home dialysis designation.</td>
</tr>
<tr>
<td>§97.244(c)(2)</td>
<td>Qualifications of the supervising nurse and alternate supervising nurse for agencies with the home dialysis designation.</td>
</tr>
<tr>
<td>§97.245(a)-(b)(1)-(10) separate penalties</td>
<td>Enforcement of staffing policies that govern all personnel used by the agency.</td>
</tr>
<tr>
<td>§97.247(a)-(b)(1)-(10) and (5)(A)-(B)-(6)(A)-(B) separate penalties</td>
<td>Verifying the employability and use of unlicensed applicants, employees and volunteers.</td>
</tr>
<tr>
<td>§97.249(c)</td>
<td>Reporting alleged acts of abuse, neglect, and exploitation of clients.</td>
</tr>
<tr>
<td>§97.250(b)(1)-(3), (c)(1)-(2), and (d)-(e) separate penalties</td>
<td>Enforcement of an agency’s written policy for investigation of known and alleged acts of abuse, neglect, and exploitation and other complaints.</td>
</tr>
</tbody>
</table>
### SEVERITY LEVEL B VIOLATIONS

$500 - $1,000 per violation

§97.602(h)(3)(E)

<table>
<thead>
<tr>
<th>Rule</th>
<th>Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>§97.251</td>
<td>Compliance with the agency's written policy to ensure that all professional disciplines comply with their respective professional practice acts or title acts for reporting and peer review.</td>
</tr>
<tr>
<td>§97.252(1)-(2)</td>
<td>An agency's financial ability to carry out its functions.</td>
</tr>
<tr>
<td>§97.256(1)(A)-(M) and (2) separate penalties</td>
<td>Developing, maintaining and implementing a written emergency preparedness and response plan.</td>
</tr>
<tr>
<td>§97.256(4) and (5)(A)-(B) separate penalties</td>
<td>Compliance with rules related to written records and notice of temporary changes due to an emergency or disaster.</td>
</tr>
<tr>
<td>§97.259(b)-(e) separate penalties</td>
<td>Initial educational training requirements for a first-time agency administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.259(f)</td>
<td>Documentation requirements for initial educational training of a first-time administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.260(a)</td>
<td>Annual continuing education requirements for an agency administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.260(b)</td>
<td>Continuing education requirements for an agency administrator and alternate administrator who has not served for 180 days or more immediately preceding the date of designation.</td>
</tr>
<tr>
<td>§97.260(c)</td>
<td>Documentation requirements for continuing education of an administrator and alternate administrator.</td>
</tr>
<tr>
<td>§97.281(1)-(16) separate penalties</td>
<td>Enforcement of a written policy for client care practices.</td>
</tr>
<tr>
<td>§97.282(a)-(f)(1)-(8) and (g)-(h) separate penalties</td>
<td>Compliance with an agency policy on client conduct and responsibility and client rights.</td>
</tr>
<tr>
<td>§97.284</td>
<td>Compliance with the Clinical Laboratory Improvement Amendments of 1988.</td>
</tr>
<tr>
<td>§97.285</td>
<td>Compliance with written policies addressing infection control.</td>
</tr>
<tr>
<td>§97.285(1)(A)-(C) and (2) separate penalties</td>
<td>Enforcement and compliance with written policies on infection control.</td>
</tr>
<tr>
<td>§97.286(b)</td>
<td>Compliance with 25 TAC §§1.131-1.137 concerning the Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities.</td>
</tr>
<tr>
<td>§97.287(a)(1)-(3) and (b)-(c) separate penalties</td>
<td>An agency's Quality Assessment and Performance Improvement Program.</td>
</tr>
<tr>
<td>§97.288(a)-(b) separate penalties</td>
<td>Compliance with an agency's written policy for coordination of services and documentation requirements.</td>
</tr>
<tr>
<td>§97.289(a)-(b) separate penalties</td>
<td>An agency's use of and agreement with independent contractors and arranged services.</td>
</tr>
<tr>
<td>§97.289(c)(1) and (3) separate penalties</td>
<td>Initial searches and searches at least every 12 months of the nurse aide registry and employee misconduct registry for unlicensed staff providing services under arrangement.</td>
</tr>
<tr>
<td>§97.289(d)(1)-(2) separate penalties</td>
<td>Conducting and reviewing a criminal history check for an unlicensed person that provides services under arrangement.</td>
</tr>
<tr>
<td>§97.290(a)</td>
<td>Enforcing a written policy that backup services are available when needed.</td>
</tr>
<tr>
<td>§97.290(a)(1)-(2)</td>
<td>Documentation that a client's designee agreed to provide backup services.</td>
</tr>
<tr>
<td>§97.290(b)</td>
<td>Enforcing a written policy that clients are educated in how to access care after hours.</td>
</tr>
</tbody>
</table>
### Severity Level B Violations

$500 - $1,000 per violation

#### §97.602(h)(3)(E)

<table>
<thead>
<tr>
<th>Rule</th>
<th>Subject Matter</th>
</tr>
</thead>
<tbody>
<tr>
<td>§97.291(1)-(2) separate penalties</td>
<td>Implementing a written policy for an agency's written contingency plan.</td>
</tr>
<tr>
<td>§97.292(a)</td>
<td>Complying with the terms of a written agreement for services that the agency provided to a client or a client's family.</td>
</tr>
<tr>
<td>§97.295(a)(1)-(2) separate penalties</td>
<td>Providing a client with written notification, and notifying a client's attending physician if applicable, of transfer or discharge.</td>
</tr>
<tr>
<td>§97.295(b)</td>
<td>An agency providing written notification of a client's transfer or discharge within the required time frame.</td>
</tr>
<tr>
<td>§97.296(a)</td>
<td>Enforcement of an agency’s policy regarding acceptance of physician delegation orders.</td>
</tr>
<tr>
<td>97.296(b)</td>
<td>Information the agency must receive to accept physician delegation.</td>
</tr>
<tr>
<td>§97.297</td>
<td>Enforcement of a written policy describing protocols and procedures agency staff must follow when receiving physician orders, if applicable.</td>
</tr>
<tr>
<td>§97.297(1)</td>
<td>Countersignature of physician verbal orders.</td>
</tr>
<tr>
<td>§97.298</td>
<td>Enforcement of a written policy for ensuring compliance with the rules adopted by the Texas Board of Nursing in 22 TAC Chapter 224 (Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments) and 22 TAC Chapter 225 (RN Delegation to Unlicensed Personnel and Tasks Not Requiring Delegation in Independent Living Environments for Clients with Stable and Predictable Conditions).</td>
</tr>
<tr>
<td>§97.300(b)</td>
<td>Enforcement of a written policy for maintaining a current medication list and a current medication administration record.</td>
</tr>
<tr>
<td>§97.300(b)(1)-(2)(A)-(B) and (3) separate penalties</td>
<td>The administration of medication.</td>
</tr>
<tr>
<td>§97.303(1)-(3)(A)-(F) separate penalties</td>
<td>The possession and use of sterile water or saline, certain vaccines or tuberculin, and certain dangerous drugs.</td>
</tr>
<tr>
<td>§97.321(c)(2)</td>
<td>Maintaining adequate staff to provide and supervise services at a branch office.</td>
</tr>
<tr>
<td>§97.322(c)(2)</td>
<td>Maintaining adequate staff to provide and supervise services at an alternate delivery site.</td>
</tr>
<tr>
<td>§97.401(b)(1)-(2)(A)-B separate penalties</td>
<td>Acceptance of a client for home health services and the initiation of services.</td>
</tr>
<tr>
<td>§97.401(d)</td>
<td>Requirement that qualified personnel provide and supervise all services.</td>
</tr>
<tr>
<td>§97.401(e)</td>
<td>Requirement that all staff providing services, delegation, and supervision be employed by or be under contract with the agency.</td>
</tr>
<tr>
<td>§97.401(g)</td>
<td>Age and competency of unlicensed persons providing licensed home health services.</td>
</tr>
<tr>
<td>§97.402(a)</td>
<td>Compliance with the Medicare Conditions of Participation (Social Security Act, Title 42, Code of Federal Regulations, Part 484.)</td>
</tr>
<tr>
<td>§97.402(c)-(e) separate penalties</td>
<td>Compliance with §97.701(f) of this chapter (relating to Home Health Aides) for an agency that implements a competency evaluation program.</td>
</tr>
<tr>
<td>§97.403(a)</td>
<td>Compliance with the Social Security Act and the regulations in Title 42, Code of Federal Regulations, Part 418.</td>
</tr>
<tr>
<td>§97.403(c)</td>
<td>Enforcement of a written policy for the provision of hospice services.</td>
</tr>
<tr>
<td>§97.403(d)(1)-(3) separate penalties</td>
<td>Requirement and conditions of the medical director for an agency that provides hospice services.</td>
</tr>
<tr>
<td>Rule</td>
<td>Subject Matter</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
</tr>
<tr>
<td>§97.403(e)(1)(A)-(D) separate penalties</td>
<td>Composition of an interdisciplinary team or teams.</td>
</tr>
<tr>
<td>§97.403(e)(2)(A)-(D) separate penalties</td>
<td>Responsibilities of the interdisciplinary team.</td>
</tr>
<tr>
<td>§97.403(e)(4)</td>
<td>Designating a registered nurse to coordinate implementation of the plan of care for each client.</td>
</tr>
<tr>
<td>§97.403(f)(1)</td>
<td>Ensuring continuity of client and family care in home and outpatient and inpatient settings.</td>
</tr>
<tr>
<td>§97.403(f)(2)</td>
<td>Contract requirements for providing arranged services.</td>
</tr>
<tr>
<td>§97.403(f)(3)</td>
<td>Professional management responsibility for arranged services.</td>
</tr>
<tr>
<td>§97.403(f)(5)</td>
<td>Ensuring that inpatient care is furnished only in a licensed facility and according to contract requirements.</td>
</tr>
<tr>
<td>§97.403(g)(1)-(3) separate penalties</td>
<td>Time requirements for contacting the client or client's representative, performing the initial health assessment visit, and initiation of services.</td>
</tr>
<tr>
<td>§97.403(h)</td>
<td>Performing and making available to each client a comprehensive health assessment that identifies the client's needs.</td>
</tr>
<tr>
<td>§97.403(h)(1)</td>
<td>Completing the comprehensive health assessment in a timely manner.</td>
</tr>
<tr>
<td>§97.403(h)(2)(A)-(C) separate penalties</td>
<td>Composition of the comprehensive health assessment.</td>
</tr>
<tr>
<td>§97.403(h)(3)(A)-(B) separate penalties</td>
<td>Requirement for updating and revising the comprehensive health assessment.</td>
</tr>
<tr>
<td>§97.403(i)(1)-(3) separate penalties</td>
<td>Requirements for a written plan of care.</td>
</tr>
<tr>
<td>§97.403(m)</td>
<td>Ensuring that all core services are provided, and requirements for using contracted staff, if necessary.</td>
</tr>
<tr>
<td>§97.403(n)(1)-(3) separate penalties</td>
<td>Requirements for providing nursing care and services.</td>
</tr>
<tr>
<td>§97.403(o)</td>
<td>Qualifications of the social worker performing hospice services.</td>
</tr>
<tr>
<td>§97.403(p)</td>
<td>Requirements for ensuring that general medical needs of clients are met.</td>
</tr>
<tr>
<td>§97.403(q)(1)-(4) separate penalties</td>
<td>Requirements for providing counseling services.</td>
</tr>
<tr>
<td>§97.403(r)</td>
<td>Requirements for providing services, maintaining a system for ensuring identification of client needs, communication across all disciplines, and integration of services.</td>
</tr>
<tr>
<td>§97.403(s)</td>
<td>Requirements for having therapy services available.</td>
</tr>
<tr>
<td>§97.403(t)</td>
<td>Requirements for having home health aide and homemaker services available.</td>
</tr>
<tr>
<td>§97.403(t)(1)-(2) separate penalties</td>
<td>Requirements for RN supervisory visits to assess aide services.</td>
</tr>
<tr>
<td>§97.403(u)(1)-(3) separate penalties</td>
<td>Requirements for providing medical supplies, appliances, and medications, as needed, for palliation and management of terminal illness and related conditions.</td>
</tr>
<tr>
<td>§97.403(v)</td>
<td>Requirements that inpatient care be available for pain control, symptom management, and respite.</td>
</tr>
<tr>
<td>§97.403(v)(1)</td>
<td>Requirements for providing inpatient care.</td>
</tr>
<tr>
<td>Rule</td>
<td>Subject Matter</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
</tr>
<tr>
<td>§97.403(v)(2)(A)-(B) separate penalties</td>
<td>Requirements for a quality assessment and performance improvement plan for hospice services.</td>
</tr>
<tr>
<td>§97.403(w)(1)(A)-(B) separate penalties</td>
<td>Requirements for having on-site 24-hour nursing services provided by RNs and LVNs.</td>
</tr>
<tr>
<td>§97.403(w)(2)(A)-(G) separate penalties</td>
<td>Implementation of a written disaster preparedness and response plan for a freestanding hospice in the event of a disaster.</td>
</tr>
<tr>
<td>§97.403(w)(3) separate penalties</td>
<td>Meeting all federal, state, and local laws, regulations, and codes pertaining to health and safety.</td>
</tr>
<tr>
<td>§97.403(w)(4) separate penalties</td>
<td>Meeting the National Fire Protection Association Life Safety Code for fire in buildings and structures.</td>
</tr>
<tr>
<td>§97.403(w)(9) separate penalties</td>
<td>Having available at all times a quantity of linen essential for proper care of clients and requirements to prevent the spread of infection on linens.</td>
</tr>
<tr>
<td>§97.403(w)(10) separate penalties</td>
<td>Making provisions for isolating clients with infectious diseases.</td>
</tr>
<tr>
<td>§97.403(w)(12)(A)-(I) separate penalties</td>
<td>Methods and procedures for dispensing and administering medications.</td>
</tr>
<tr>
<td>§97.404(c) separate penalties</td>
<td>Qualifications of agency staff performing personal assistance services.</td>
</tr>
<tr>
<td>§97.404(d) separate penalties</td>
<td>Tasks authorized under a personal assistance services license category.</td>
</tr>
<tr>
<td>§97.404(g) separate penalties</td>
<td>Enforcement of a written policy that addresses the supervision of agency personnel with input from the client or family on the frequency of supervision.</td>
</tr>
<tr>
<td>§97.404(g)(1)-(2) separate penalties</td>
<td>Conditions and qualifications for supervising agency personnel delivering personal assistance services.</td>
</tr>
<tr>
<td>§97.404(h)(1)-(5) separate penalties</td>
<td>Performance of gastrostomy tube feedings and medication administration for an agency that provides personal assistance services.</td>
</tr>
<tr>
<td>§97.405(a) separate penalties</td>
<td>Requirements for agencies that provide peritoneal dialysis or hemodialysis services.</td>
</tr>
<tr>
<td>§97.405(c)(1)-(2) separate penalties</td>
<td>Qualifications and responsibilities of the medical director for an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(e)(1)(A)-(C) separate penalties</td>
<td>Provision and supervision of nursing services for an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(e)(2) separate penalties</td>
<td>Provision of nutritional counseling for an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(e)(3) separate penalties</td>
<td>Provision of medical social services for an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(f)(1) separate penalties</td>
<td>Requirements for orientation and training of personnel providing direct care to clients receiving home dialysis services.</td>
</tr>
<tr>
<td>§97.405(f)(2)(A)-(G) separate penalties</td>
<td>Requirement for an orientation and skills education period for licensed nurses.</td>
</tr>
<tr>
<td>§97.405(i) separate penalties</td>
<td>Requirement that an agency coordinate the exchange of medical and other important information when transferring a home dialysis client to a health-care facility for treatment.</td>
</tr>
<tr>
<td>§97.405(k) separate penalties</td>
<td>Requirement for routine hepatitis testing of home dialysis clients and agency employees providing dialysis care.</td>
</tr>
<tr>
<td>§97.405(k)(1)(A)-(C) separate penalties</td>
<td>Requirements for hepatitis B screening and vaccinations for staff.</td>
</tr>
<tr>
<td>§97.405(k)(2)(A)-(E) separate penalties</td>
<td>Requirements for hepatitis B screening and vaccinations for clients.</td>
</tr>
<tr>
<td>Rule</td>
<td>Subject Matter</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
</tr>
<tr>
<td>§97.405(l)</td>
<td>Requirements for employees providing direct care to clients to have a current CPR certification.</td>
</tr>
<tr>
<td>§97.405(m)</td>
<td>Requirement for initial admission assessment of a client for home dialysis services.</td>
</tr>
<tr>
<td>§97.405(n)</td>
<td>Requirement for development of a long-term program for a client receiving home dialysis services.</td>
</tr>
<tr>
<td>§97.405(o)</td>
<td>Requirement that the agency conducts a history and physical of a home dialysis client at admission and annually.</td>
</tr>
<tr>
<td>§97.405(p)(1)-(2) separate penalties</td>
<td>Requirement for physician orders for home self-assisted dialysis treatment.</td>
</tr>
<tr>
<td>§97.405(q)(1)-(7) separate penalties</td>
<td>Requirements for development and implementation of a care plan for a home dialysis client.</td>
</tr>
<tr>
<td>§97.405(r)</td>
<td>Requirement for medication administration by licensed personnel for an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(s)(2)-(3) separate penalties</td>
<td>Additional requirements for maintaining client records in an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.405(t)(1)-(4) separate penalties</td>
<td>Requirements for use of water in the home dialysis setting.</td>
</tr>
<tr>
<td>§97.405(u)</td>
<td>Adoption and enforcement of a policy to test dialysis equipment prior to each treatment.</td>
</tr>
<tr>
<td>§97.405(v)</td>
<td>Enforcing the agency’s written preventive maintenance program for home dialysis equipment.</td>
</tr>
<tr>
<td>§97.405(v)(1), (1)(A), (1)(C)-(D), and (2) separate penalties</td>
<td>Implementing requirements for a written preventive maintenance program for home dialysis equipment.</td>
</tr>
<tr>
<td>§97.405(w)(1)-(6) separate penalties</td>
<td>Reuse of disposable medical devices in the home dialysis setting.</td>
</tr>
<tr>
<td>§97.405(x)(1)-(2)</td>
<td>Provision of laboratory services.</td>
</tr>
<tr>
<td>§97.405(x)(3)-(4) separate penalties</td>
<td>Provision of laboratory services.</td>
</tr>
<tr>
<td>§97.405(y)(1)-(2) separate penalties</td>
<td>Supplies for home dialysis services.</td>
</tr>
<tr>
<td>§97.405(z)(1)-(7) separate penalties</td>
<td>Compliance with policies and procedures for medical emergencies and emergencies resulting from a disaster required of an agency that provides home dialysis services.</td>
</tr>
<tr>
<td>§97.406(2)-(5) separate penalties</td>
<td>Provision of psychoactive services.</td>
</tr>
<tr>
<td>§97.407(1)-(11) separate penalties</td>
<td>Provision of intravenous therapy services.</td>
</tr>
<tr>
<td>§97.523(e)</td>
<td>Requirement to grant the surveyor entry to the agency if closed when the surveyor arrives during regular business hours.</td>
</tr>
<tr>
<td>§97.701(a)-(f)(1)-(7) separate penalties</td>
<td>Home health aides.</td>
</tr>
</tbody>
</table>