

EXHIBIT E-4

DEPARTMENT OF HEALTH

SUBJECT: Rules & Regulations for Private Care Agencies

DESCRIPTION: This change adds a new citation of authority.

PUBLIC COMMENT: A public hearing was held December 10, 2009, and the public comment period expired at that time. No public comments were submitted to the Department regarding the proposed rule. The proposed effective date is May 1, 2010.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Arkansas Code § 20-10-2204 (Act 5 of 2009) specifically authorizes the Board of Health to "promulgate rules necessary to implement" the chapter regarding personal care service providers and to "establish a separate licensure category for private care agencies that provide personal care services twenty-four (24) hours a day and seven (7) days a week."

EXHIBIT E-4

Draft 11-3-09

Agency # 007.05

RULES AND REGULATIONS FOR PRIVATE CARE AGENCIES IN ARKANSAS



ARKANSAS DEPARTMENT OF HEALTH
20107

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ARKANSAS

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SECTION 1: PREFACE

These rules and regulations have been prepared for the purpose of establishing a criterion for minimum standards for the licensure of Private Care Agencies providing Medicaid Personal Care in Arkansas. By necessity they are of a regulatory nature but are considered to be practical minimal design and operational standards for these facilities. These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent. However, it is expected that facilities will exceed these minimum requirements and that they will not be dependent upon future revisions in these standards as a necessary prerequisite for improved services. Each Private Care Agency has a strong moral responsibility for providing optimum patient care and treatment for the patients it serves.

SECTION 2: AUTHORITY

The following Rules and Regulations for Private Care Agencies in Arkansas are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas in Act 1537 of 1999, Section 133 and Act 17 of 2003 (First Extraordinary Session); Act 5 of 2009; Ark. Code Ann. § 20-10-2201 et seq.

SECTION 3: PURPOSE

In accordance with Act 1537 of 1999, Section 133 and Act 17 of 2003 (First Extraordinary Session), Act 5 of 2009; Ark. Code Ann. § 20-10-2201 et seq.; rules, regulations and minimum standards for Private Care Agencies operating in the State of Arkansas are hereby established. These rules will ensure high quality professional care for patients in their home by providing for the safe, appropriate care of all admitted to a private care agency's program regardless of setting and shall apply to both new and existing agencies.

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SECTION 4: DEFINITIONS

The following words and terms, when used in these sections, shall have the stated meanings, unless the context clearly indicates otherwise.

- A. Administrator – A person who is an agency employee and is a physician, registered nurse, or an individual with at least one year of supervisory or administrative experience in home health care or in related health provider programs.
- B. Assistance with Medication – Ancillary aid needed by a patient to self-administer medication, such as reminding a patient to take a medication at the prescribed time, opening and closing a medication container, and returning a medication to the proper storage area. Such ancillary aid shall not include administration of any medication by injection, inhalation, ingestion, or any other means, calculation of a patient's medication dosage, or altering the form of the medication by crushing, dissolving, or any other method.
- C. Branch Office – A location or site from which a private care agency provides services within a portion of the total geographic area served by the primary agency. The branch office is part of the primary agency and is located sufficiently close (within a 50 mile radius) to share administrative supervision and services in a manner that render it unnecessary to obtain a separate license as a home health agency. A branch office shall have at least one registered nurse assigned to that office on a full time basis. The registered nurse may be an employee or a contracted individual.
- D. Clinical Note – A dated, written or electronic and signed notation by agency personnel of a contact with a patient including a description of signs and symptoms, treatment and/or medication given, the patient's response, other health services provided, and any changes in physical and/or emotional condition.
- E. Clinical Record – An accurate account of services provided for each patient and maintained by the agency in accordance with accepted medical standards.
- F. Contractor – An entity or individual providing services for the agency who does not meet the definition of employee.
- G. Coordinating – Bringing needed services into a common action, movement or condition for the health of the patient.
- H. Department – The Arkansas Department of Health, Health Facility Services.
- I. Discharge Summary – A recapitulation of all services provided by the private care agency before discharge of a patient.

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- J. Employee – Any individual for whom the agency is required to issue a form W-2.
- K. Geographic Area – The land area, for which the agency shall be licensed, consisting of not more than a 50 mile radius surrounding the private care agency's primary location.
- L. Health – The condition of being sound in body, mind and spirit, especially freedom from physical disease or pain.
- M. Health Assessment – A determination of a patient's physical and mental status performed by medical professionals.
- N. Licensed Practitioner – An individual permitted by law and by the Private Care Agency to prescribe care.
- O. Personal Care Aide – A person who provides personal care/personal services for a person in the home under the supervision of a registered nurse.
- P. Maintenance – To keep in an existing state.
- Q. Parent Agency – The agency physically located within the state that develops and maintains administrative control of branches.
- R. Patient Care Conference – A documented conference among the agency staff or contractors providing care to a patient to evaluate patient care needs and the delivery of service.
- S. Personal Care – Health related assistance in activities of daily living, hygiene and grooming for the sick or debilitated.
- T. Physician – A person who is currently licensed under the Arkansas Medical Practices Act.
- U. Place of Business – Any office of a private care agency that maintains patient records or directs services. This shall include a suboffice, a branch office, or any other subsidiary location.
- V. Plan of Care – A written plan which specifies scope, frequency and duration of services that is signed by a physician or licensed practitioner.
- W. Preventive – To keep from happening or existing.
- X. Primary Agency – The agency physically located within the state responsible for the service rendered to patients and for implementation of plan of care.

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- Y. Private Care Agency – providers licensed by the Department of Labor, certified as ElderChoices Providers and who furnish in-home staffing services for respite, chore services, and homemaker services and are covered by liability insurance of not less than one million dollars (\$1,000,000.00) covering their employees and independent contractors while they are engaged in providing services, such as personal care, respite, chore services, and homemaker services.
- Z. Quality of Care – Clinically competent care which meets professional standards, supported and directed in a planned pattern to achieve maximum dignity at the required level of comfort, preventive health measures and self management.
- AA. Registered Nurse – A person who is currently licensed under laws of Arkansas to use the title, Registered Nurse.
- BB. Rehabilitative – To restore or bring to a condition of health or useful and constructive activity.
- CC. Residence – A place where a person resides, including a home, nursing home, residential care facility or convalescent home for the disabled or aged.
- DD. Restorative – Something that serves to restore to consciousness, vigor or health.
- EE. Service Area – The land area for which the agency shall be licensed, which shall be consistent with their Certification of Need (CON) or Permit of Approval (POA), if one is required, but in no case shall the service area consist of more than a 50 mile radius from the agency's primary location.
- FF. Subunit – A semi-autonomous organization, which serves patients in a geographic area different from that of the parent agency. The subunit by virtue of the distance between it and the parent agency is judged incapable of sharing administration, supervision, and services on a daily basis with the parent agency and shall, therefore independently meet the regulations and standards for licensure. A subunit may not have a branch office. The parent agency of the subunit shall be located and licensed within the state.
- GG. 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.

SECTION 5: UNREGULATED AGENCY

No Private Care Agency shall provide personal care services in the State of Arkansas without a licensed fully operational physical location within the State. The Authority is vested with the Director to determine if an agency is subject to regulation under the statute and is inherent in the responsibility to regulate private care agencies that are within the definitions of Act-1537; Section-133.

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SECTION 6: APPLICATION FOR LICENSE

- A. Annual license applications for a Private Care Agency shall be on forms prescribed by the Department and shall be effective on a calendar year basis with an expiration date of December 31.
- B. Each agency shall receive a license for Medicaid Personal Care.
- C. No license shall be transferred from one entity to another. If a person, partnership, organization or corporation is considering acquisition of a private care agency, in order to insure continuity of patient services, the entity shall submit a license application at least 60 days prior to the acquisition for each place of business.
- D. No license shall be transferred from one location to another without prior approval from Health Facility Services as provided in this subsection. If an agency is considering relocation, the agency shall complete and submit a form provided by Health Facility Services 30 days prior to the intended relocation.
 - 1. A relocation shall be approved by Health Facility Services if the new location is within the existing service area.
 - 2. All other relocations shall not be approved, and the licensee shall submit a new application for a license.
 - 3. The agency shall notify Health Facility Services of any of the following:
 - a. Notification of termination of provision of services;
 - b. Any change in telephone number;
 - c. Any name changes in the agency within five working days after the effective date of the name change; and
 - d. Address changes.

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SECTION 7: INSPECTIONS

- A. An onsite inspection shall determine if standards for licensure are being met before the initial license is issued.
- B. Once the initial inspection is conducted and the agency becomes licensed, subsequent inspections shall be conducted on an every year or every three year basis. Agencies which are placed on a yearly cycle will be those meeting one or more of the following provisions:
 - 1. Agencies which have been licensed for less than three years;
 - 2. Agencies which have had a change of ownership or a significant change in management staff;
 - 3. Agencies who have had a substantiated complaint since the last inspection; and
 - 4. Agencies which received deficiencies during the last inspection.

Agencies not meeting any of the above provisions shall be placed on a three year survey cycle.

- C. If the inspection is conducted in order to determine compliance with standards, the agency shall come into compliance within 60 days. An on site follow-up visit or a follow-up by mail shall be conducted to determine if deficiencies have been corrected. If the agency fails to comply, the Director may propose to suspend or revoke the license in accordance with the section relating to License Denial, Suspension, or Revocation.

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SECTION 8: DENIAL, SUSPENSION, REVOCATION OF LICENSE

- A. Health Facility Services may deny issuing a license to an agency if the agency fails to comply with these rules.
- B. Health Facility Services may suspend the license of an agency for one or more of the following reasons:
 - 1. Violation of the provisions of the statute or any of the standards in these rules;
 - 2. Misstatement of a material fact on any documents required to be submitted to Health Facility Services or requirements to be maintained by the agency pursuant to these rules;
 - 3. Commission by the agency or its personnel of a false, misleading, or deceptive act or practice;
 - 4. Materially altering any license issued by the Department.
- C. Health Facility Services may revoke the license of any agency for one or more of the following reasons:
 - 1. A repeat violation within a 12 month period which resulted in a license suspension; or
 - 2. An intentional or negligent act by the agency or its employees which materially affects the health and safety of a patient.
- D. If the Director of Health Facility Services of the Department proposes to deny, suspend, or revoke a license, the Director shall notify the agency of the reasons for the proposed action and offer the agency an opportunity for a hearing. The agency may request a hearing within 30 days after the date the agency receives notice. The request shall be in writing and submitted to the Director, Health Facility Services, Arkansas Department of Health, 5800 West Tenth, Suite 400, Little Rock, Arkansas, 72204. A hearing shall be conducted pursuant to the Administrative Procedures Act. If the agency does not request a hearing in writing after receiving notice of the proposed action, the agency is deemed to have waived the opportunity for a hearing and the proposed action shall be taken.
- E. Health Facility Services may suspend or revoke a license to be effective immediately when the health and safety of patients are threatened. Health Facility Services shall notify the agency of the emergency action and shall notify the agency of the date of a hearing, which shall be within seven day of the effective date of the suspension or revocation. The hearing shall be conducted

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pursuant to the Administrative Procedures Act.

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SECTION 9: BRANCH OFFICES

- A. The agency shall notify the Department in writing in advance of the plan to establish a branch office. Included in the notification shall be a description of the services to be provided (must be the same as the parent agency), the geographic area to be serviced by the branch office and a description of exactly how supervision by the parent agency will occur. All branch offices shall be subject to approval by Health Facility Services. Once the agency receives approval by Health Facility Services to establish the requested branch office the agency shall notify Health Facility Services of the branch office address, telephone number, and the name of the registered nurse supervisor.
- B. Onsite supervision of the branch office shall be conducted by the parent/primary agency at least every two months. The supervisory visits shall be documented and include the date of the visit, the content of the consultation, the individuals in attendance, and the recommendations of the staff. In addition, branch supervision shall include clinical record review of the branch records, inclusion in the agency's quality assurance activities, meetings with the branch supervisor, and home visits.
- C. A full-time registered nurse shall be assigned to the branch office and shall be available during all operating hours.
- D. All admissions shall be coordinated through the parent/primary agency and a current roster of patients shall be maintained by the parent agency at all times.
- E. A branch office shall offer the same services as those offered by the parent/primary agency.

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SECTION 10: GENERAL REQUIREMENTS

A. Operational Policies

1. The agency shall have a written plan of operation including:
 - a. Organizational chart showing ownership and line of authority down to the patient care level;
 - b. The services offered, including hours of operation and lines of delegation of responsibility down to the patient care level;
 - c. Criteria for patient acceptance referral, transfer and termination;
 - d. Evidence of direct administrative and supervisory control and responsibility for all services including services provided by branch offices;
 - e. An annual operating budget approved by the governing body; and
 - f. Written contingency plan in the event of dissolution of the agency.
2. Policies shall be developed and enforced by the agency and include the following:
 - a. Orientation of all personnel to the policies and objectives of the agency;
 - b. Participation by all employees and/or contracted individuals in appropriate staff development programs, including a specific policy on the number of in service hours that will be required for registered nurses and aides.
 - c. Periodic evaluation of agency staff and/or contracted individuals' performance;
 - d. Personnel policies;
 - e. Patient care policies;
 - f. Disciplinary actions and procedures;
 - g. Job description (statement of those functions which constitute job requirements) and job qualifications (specific education and training necessary to perform the job) for each position with the agency; and

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monitored and corrected;

- b. Adopt and periodically review written bylaws or an acceptable equivalent'
 - c. Approve written policies and procedures related to safe, adequate services and operation of the agency with annual or more frequent review by administrative or supervisory personnel;
 - d. Appoint an administrator and approve a plan for an alternate in the absence of the administrator.
 - e. Oversee the management and fiscal affairs of the agency; and
 - f. Approve a method of obtaining regular reports on participant satisfaction.
2. The governing board shall insure the agency has an administrator who is an employee of the agency or related institution to:
- a. Organize and direct the agency's ongoing functions;
 - b. Maintain an ongoing liaison between the governing body and the personnel;
 - c. Ensure all persons providing services on behalf of the agency are qualified and receive ongoing education;
 - d. Ensure the accuracy of public information materials and activities;
 - e. Implement a budgeting and accounting system; and
 - f. Ensure the presence of an alternate administrator to act in the administrator's absence.
3. The governing board shall be responsible for ensuring the agency has a full-time supervising registered nurse to supervise clinical services. Full-time shall be according to established business hours of the agency. The administrator and supervising nurse may be the same individual.
4. If a licensed agency contracts with another entity for services, the governing body shall ensure that administration; patient management and supervision down to the patient care level are ultimately the responsibility of the licensed agency.

C. Services Provided by Contractors

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Private Care Agencies arranging for services to be provided by independent contractors or other entities there shall be a written agreement which specifies the following;

1. All referrals are through the primary agency and patients are accepted for care only by the primary agency;
2. The services to be provided;
3. A contracted entity or contracted individual conforms to all applicable agency polices, including those described in Section 10.A.2;
4. The primary agency is responsible for reviewing, approving and assuring the implementation of the plan of treatment;
5. The manner in which services will be controlled, coordinated and evaluated by the primary agency;
6. The procedures for submitting medical record documentation and scheduling of staff;
7. The procedure for how changes in the aide care plan will be communicated between the contracted individual or entity'; and
8. The procedures for determining charges and reimbursement.

D. Quality Improvement

1. An agency shall adopt, implement and enforce a policy on a quality improvement program which provides for accountability and desired outcomes.
2. Those responsible for the quality improvement program shall:
 - a. Implement and report on activities and mechanisms for monitoring the quality of care;
 - b. Identify, and when possible, resolve problems; and
 - c. Make suggestions for improving care.
3. As part of the quality improvement program a clinical record review shall be conducted at least quarterly by appropriate professionals. A minimum of ten percent of both active and closed records shall be reviewed or a minimum of ten records per quarter if the case load is less than 99. The

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purpose of the clinical record review is to evaluate all services provided for consistency with professional practice standards for private care agencies and the agency's policies and procedures, compliance with the plan of care, the appropriateness, effectiveness and adequacy of the services offered, and evaluations of anticipated patient outcomes. Evaluations shall be based on specific record review criteria that are consistent with the agency's admission policies and other agency specific care policies and procedures.

E. Patient Rights

1. The agency shall provide each patient and family with a copy of the Bill of Rights affirming the patient's right to:
 - a. Be informed of the services offered by the agency and those being provided to the patient;
 - b. Participate in the development of the plan of care and to be informed of the dates and approximate time of service;
 - c. Receive an explanation of any responsibilities the participant may have in the care process;
 - d. Be informed of the name of agency and how to contact that agency during all hours of operation;
 - e. Be informed of the process for submitting and addressing complaints to the agency and be notified of the State Home Health Hotline number.
 - f. Be informed orally and in writing of any charges which insurance might not cover and for which the patient would be responsible;
 - g. Courteous and respectful treatment, privacy and freedom from abuse and discrimination';
 - h. Confidential management of participant records and information;
 - i. Access information in the participant record upon request; and
 - j. Receive prior notice and an explanation for the reasons of termination, referral, transfer, discontinuance of service or change in the plan of care.
2. The agency shall provide each patient and family with a written list of

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responsibilities affirming the patient's responsibility to:

- a. Assist in developing and maintaining a safe environment;
- b. Treat all agency staff with courtesy and respect;
- c. Participate in the development and update of the plan of care;
- d. Adhere to the plan of care or services as developed by the agency and to assist in the care as necessary.

F. Advance Directives

1. The agency shall have written policies and procedures regarding advance directives.
2. The agency shall inform and distribute written information to each patient on the initial evaluation visit concerning its policies on advance directives. Written information shall include notifying patients of their right to:
 - a. Make decisions about their medical care;
 - b. Accept or refuse medical or surgical treatment; and
 - c. Formulate, at the individual's option, an advance directive.
3. The agency shall document in the patient's medical record whether he/she has executed an advance directive.

G. Services Provided

All services shall be rendered and supervised by qualified personnel. A private Care Agency shall provide Personal Care Services. A personal care aide shall be employed by or under contract to provide aide services. The aide shall be supervised by a registered nurse at least every 62 days.

If a patient is receiving services from another agency Monday thru Friday the private care agency must coordinate the services being provided in order that services are consistent. There must be documentation of communication between the home health and Private Care Agency.

H. Personal Care Aide Services

1. Each personal care aide shall meet at least one of the following requirements:

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- a. Have at least one year of experience in an institutional setting (home health agency, hospital, hospice, or long-term care facility). This experience shall be verified by a previous employer;
- b. Have a certificate issued by the State of Arkansas for working in long-term care facilities. A copy of this certificate shall be available for review; or
- c. Have completed a 40 hour aide training course that meets requirements set forth in these

NOTE: In lieu of the requirement for completion of the home health aide training course, a nursing student may qualify as a home health aide by submitting documentation from the Director of programs and/or the Dean of a School of Nursing that states that the nursing student has demonstrated competency in providing basic nursing care in accordance with the school's curriculum.

2. The agency is responsible for evaluating the competency of any aide who has not been employed as an aide in an institutional setting in the last 24 months. At a minimum, the aide shall be observed by a registered nurse performing the skills required to care for a patient including bathing, transferring, range of motion exercises, toileting, dressing, nail care and skin care. The registered nurse shall observe the aide performing these skills on a person. Any other tasks or duties for which the aide may be responsible may be evaluated by written test, oral test or observation. There shall be documentation by the agency to show evidence of this evaluation.
3. A registered nurse shall complete an aide assignment sheet for each patient receiving aide services. Each aide caring for the patient shall receive a copy of the assignment sheet and provide services as assigned. A copy of the assignment sheet shall be left in the patient's home.
4. Each aide assignment sheet shall be individualized and specific according to the patient's needs
5. The registered nurse shall conduct a visit to the patient's place of residence at least every 62 days to supervise the aide and update the aide assignment sheet.
6. In no event shall a personal care aide be assigned to receive or reduce to writing orders from a physician or licensed practitioner. An aide shall not perform any sterile procedure or any procedure requiring the application of medication requiring a prescription.
7. Upon a request by a patient and/or family member for assistance with

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medications, the registered nurse may assign a home health aide to assist with oral medications which are normally self-administered. Assistance shall be limited to reminding a patient to take a medication at a prescribed time, opening and closing a medication container and returning a medication to a proper storage area.

8. Except as otherwise provided in these rules, duties of the home health aide may include:
 - a. Personal care: bathing, grooming, feeding, ambulation, exercise, oral hygiene, and skin care;
 - b. Assistance with medications ordinarily self-administered as assigned;
 - c. Household services essential to health care in the home;
 - d. Completion of records and reporting to appropriate supervisor;
 - e. Charting intake and output; and
 - f. Any duty consistent with the State Board of Nursing Regulations on Delegation of Duties may be assigned by a registered nurse to meet the individual needs of the patient.
 - g. a. A minimum of 40 hours of classroom and clinical instruction related particularly to the home health setting;
 - h. b. Written course objectives with expected outcomes and methods of evaluation; and
 - i. c. An assessment that the student knows how to read and write English and to carry out directions.
9. If the training is provided by the agency, the training program for personal care aides shall be conducted under the supervision of a registered nurse. The training program may contain other aspects of learning, but shall include the following:
10. Course and clinical work content shall include, but not be limited to, bathing, ambulation and exercise, personal grooming, principles of nutrition and meal preparation, health conditions, developmental stages and mental status, household services essential to health care at home, assistance with medication, safety in the home, completion of appropriate records and reporting changes to appropriate supervisor.

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11. Aides shall receive a minimum of 12 hours of inservice training per 12 months. The inservices provided shall address areas that directly relate to the patient care aspects of the aide's job.
- I. Records and Documentation
 1. The private care agency shall maintain records which are orderly, intact, legibly written and available and retrievable either in the agency or by electronic means and suitable for photocopying or printing.
 2. Records shall be stored in a manner which:
 - a. Prevents loss or manipulation of information;
 - b. Protects the record from damage; and
 - c. Prevents access by unauthorized persons.
 3. Records shall be retained for a minimum of five years after discharge of the patient or two years after the age of majority.
 4. Each record shall include:
 - a. Appropriate identifying information;
 - b. Initial assessment (performed by a registered nurse;
 - c. Plan of care (which shall include as applicable, medication, dietary, treatment, activities);
 - d. Clinical notes; and
 - e. Acknowledgment of receiving information regarding advance directive;
 5. The following shall be included, if applicable;
 - a. Physician or licensed practitioner orders;
 - b. Records of supervisory visits;
 - c. Records of case conferences; and
 - d. Discharge summary

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6. Clinical notes are to be written the day the service is rendered and incorporated into the record no less than every 14 days.
7. Provisions shall be made for the protection of records in the event an agency ceases operation.

J. Discharge Planning

There shall be a specific plan for discharge in the clinical record and there must be ongoing discharge planning with the patient.

K. Complaints

Each agency shall keep a record of complaints received. Documentation shall be kept on each complaint regarding the name of the complainant, the relationship to the patient (if applicable), the nature of the complaint, and the action taken to resolve the complaint.

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SECTION 11: STANDARDS FOR PERSONAL CARE SERVICES

- A. The registered nurse shall perform an initial evaluation visit within five days of a specific request for personal care aide services.
- B. If the agency cannot perform an initial evaluation visit within five days of a specific request for services, there shall be documentation regarding the reason, the anticipated date the evaluation will be conducted, and notification of the patient regarding when the evaluation will be performed.
- C. If the agency does not have services available at the time of the initial evaluation, the agency shall explain this to the patient. If the agency cannot staff the case within two weeks of the initial evaluation, the agency shall be responsible for contacting other agencies in the area to determine if services are available. If another agency can provide the services in a shorter length of time, the patient shall be informed and given the choice of changing agencies.
- D. If an aide misses a scheduled visit, there shall be documentation that the patient was contacted prior to the missed visit. Every attempt shall be made to send a substitute aide to provide care.
- E. For individuals receiving personal care services only, the agency is not required to have the plan of care signed by a physician or licensed practitioner, unless otherwise required by other agencies or laws. However, a plan of care shall be developed outlining the scope, frequency and duration of services.
- F. If care is ordered per hour, the aide shall document the time the aide arrived at the home and the time the aide departed.
- G. Each aide shall document the tasks that were performed. If a task is not completed there shall be a documented reason why. Patient care problems noted by the aide during the course of care shall be reported to the registered nurse.
- H. The registered nurse shall make a visit to each patient's home at least every 62 days to supervise aide services. A registered nurse shall be available for consultation during operating hours.