

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 26 - HOME CARE AGENCIES

6 CCR 1011-1 Chap 26

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Copies of these regulations may be obtained at cost by contacting:

Division Director
Colorado Department of Public Health and Environment
Health Facilities Division
4300 Cherry Creek Drive South
Denver, Colorado 80222-1530
Main switchboard: (303) 692-2800

These chapters of regulation incorporate by reference (as indicated within) material originally published elsewhere. Such incorporation, however, excludes later amendments to or editions of the referenced material. Pursuant to 24-4-103 (12.5), C.R.S., the Health Facilities Division of the Colorado Department of Public Health And Environment maintains copies of the incorporated texts in their entirety which shall be available for public inspection during regular business hours at:

Division Director
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Section 1. STATUTORY AUTHORITY AND APPLICABILITY

- 1.1 The statutory authority for the promulgation of these rules is set forth in Sections 25-1.5-103 and 25-27.5-101, *et seq.*, C.R.S.
- 1.2 A home care agency, as defined herein, shall comply with all applicable federal and state statutes and regulations, including but not limited to, the following:
 - (a) This Chapter XXVI as it applies to the type of services provided.
 - (b) 6 CCR 1011-1, Chapter II, General Licensure Standards, unless otherwise modified herein.

Section 2. GENERAL PROVISIONS

- 2.1 The purpose of these rules is to implement Title 25, Article 27.5 of the Colorado Revised Statutes and to protect and promote the health and welfare of home care consumers through the establishment and enforcement of regulations setting minimum standards for home care services that do not infringe on accessibility or affordability while maintaining accountability to help ensure the safety and well-being of home care consumers.

Section 3. DEFINITIONS

- 3.1 "Authorized representative" means an individual responsible for the private payment of home care services or an individual who possesses written authorization from the consumer to represent his or her interests regarding care, treatment and services provided by the HCA. The authorized representative shall not be the home care consumer's service provider except as allowed by state Medicaid programs.
- 3.2 "Branch office" means a location or site from which a home care agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home care agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the requirements of this chapter.
- 3.3 "Bylaws" means a set of rules adopted by a home care agency for governing the agency's operation.
- 3.4 "Certified home care agency" means an agency that is certified by either the federal Centers for Medicare and Medicaid Services (CMS) or the state Department of Health Care Policy and Financing (HCPF) to provide skilled home health or personal care services.
- 3.5 "Clinical note" means a written notation of a healthcare contact with a consumer that is signed, with date and time, by an employee of the home care agency that describes signs and symptoms; treatment; education; drugs administered and the consumer's reaction; and any changes in physical or emotional condition.
- 3.6 "Community Centered Board" means a private corporation, for profit or not for profit. That. When designated pursuant to section 27-10.5-105, C.R.S., provides cases management services to persons with developmental disabilities, is authorized to determine eligibility of those persons to receive services and supports under C.R.S. Title 27, article 10.5, and provides authorized services and supports to those persons either directly or by purchasing services and supports from service agencies.
- 3.7 "Consumer" means a person who receives skilled home health services or personal care services in his or her temporary or permanent home or place of residence from a home care agency or a provider referred by a home care placement agency.
- 3.8 "Department" means the Colorado Department of Public Health and Environment.
- 3.9 "Employee" means any person providing home care and services on behalf of the agency.
- 3.10 "Geographic area" means an area of land, for which the agency shall be licensed surrounding the home care agency's primary location. There is no restriction as to the number of agencies that may provide services in a particular geographic area.

- 3.11 "Home care agency" means any sole proprietorship, partnership, association, corporation, government or governmental subdivision or agency subject to the restrictions in Section 25-1.5-103(1)(a)(II), C.R.S., not-for-profit agency, or any other legal or commercial entity that manages and offers, directly or by contract, skilled home health services or personal care services to a home care consumer in the home care consumer's temporary or permanent home or place or residence. Home care agency is also referred to in this chapter as "HCA" or "agency."
- (A) A residential facility that delivers skilled home health or personal care services which the facility is not licensed to otherwise provide, shall either be licensed as a home care agency or require the skilled home health or personal care services to be delivered by a licensed home care agency.
- (B) "Home care agency" does not include:
- (1) Organizations that provide only housekeeping services;
 - (2) Community and rural health networks that furnish home visits for the purpose of public health monitoring and disease tracking;
 - (3) An individual who is not employed by or affiliated with a home care agency and who acts alone, without employees or contractors;
 - (4) Outpatient rehabilitation agencies and comprehensive outpatient rehabilitation facilities certified pursuant to Title XVIII or XIX of the "Social Security Act," as amended;
 - (5) Consumer-directed attendant programs administered by the Colorado Department of Health Care Policy and Financing;
 - (6) Licensed dialysis centers that provide in-home dialysis services, supplies, and equipment;
 - (7) Subject to the requirements of Section 25-27.5-103(3), C.R.S., a facility otherwise licensed by the department;
 - (8) A home care placement agency as defined in this section; or
 - (9) Services provided by a qualified early intervention service provider and overseen jointly by the Department of Education and the Department of Human Services.
- 3.12 "Home care placement agency" means an organization that, for a fee, provides only referrals of providers to home care consumers seeking services. A home care placement agency does not provide skilled home health services or personal care services to a home care consumer in the home care consumer's temporary or permanent home or place of residence directly or by contract. Such organizations shall follow the requirements of Sections 25-27.5-103(2), 25-27.5-104(1)(c), and 25-27.5-107, C.R.S., and section 4 of this chapter
- 3.13 "Informal caregiver" means a person who provides care to the consumer when the paid caregiver is not in the home.
- 3.14 "Intermediate care provider" means a nurse practitioner or physician assistant.
- 3.15 "Nurse aide" means a nurse aide certified by the Colorado Department of Regulatory Agencies or a nurse aide who has completed the requisite training and is within four (4) months of achieving certification.

- 3.16 "Parent home care agency" means the agency that develops and maintains administrative control of branch offices.
- 3.17 "Personal care services" means assistance with activities of daily living, including but not limited to bathing, dressing, eating, transferring, walking or mobility, toileting, and continence care. It also includes housekeeping, personal laundry, medication reminders, and companionship services furnished to a home care consumer in the home care consumer's temporary or permanent home or place of residence, and those normal daily routines that the home care consumer could perform for himself or herself were he or she physically capable, which are intended to enable that individual to remain safely and comfortably in the home care consumer's temporary or permanent home or place of residence.
- 3.18 "Plan of correction" means a written plan prepared by the HCA and submitted to the department for approval that specifies the measures the HCA shall take to correct all cited deficiencies.
- 3.19 "Primary agency" means the agency responsible for the consumer's direct care coordination when a secondary or subcontracted agency is also providing care and services.
- 3.20 "Qualified Early Intervention Service Provider" has the same meaning set forth in section 27-10.5-702, C.R.S.
- 3.21 "Service Agency" means an individual or any publicly or privately operated programs, organization, or business providing services or supports for persons with developmental disabilities.
- 3.22 "Service note" means a written notation that is signed, with date and time, by an employee of the home care agency furnishing the non-medical services.
- 3.23 "Skilled home health services" means health and medical services furnished in the consumer's temporary or permanent place of residence that include wound care services; use of medical supplies including drugs and biologicals prescribed by a physician; in-home infusion services; nursing services; or certified nurse aide services that require the supervision of a licensed or certified health care professional acting within the scope of his or her license or certificate; occupational therapy; physical therapy; respiratory care services; dietetics and nutrition counseling services; medication administration; medical social services; and speech-language pathology services. "Skilled home health services" does not include the delivery of either durable medical equipment or medical supplies.
- 3.24 "Subdivision" means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the licensure requirements for HCAs. A subdivision that has branch offices is considered a parent agency.
- 3.25 "Summary report" means the compilation of the pertinent factors of a home care consumer's clinical notes that is submitted to the consumer's physician by the skilled home health care agency.
- 3.26 "Supervision" means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity.

Section 4. PLACEMENT AGENCIES

4.1 Registration

- (A) On or after June 1, 2009, each home care placement agency shall notify the department in writing that it provides referrals for home care services to consumers and shall annually update such notice.
- (B) The individuals(s) responsible for the operation of any placement agency that fails to register with the department may be subject to a civil penalty assessed by the department of not less than \$500 per year or more than \$1,000 per year.

4.2 Criminal history record check

- (A) On or after June 1, 2009, the home care placement agency shall require any individual seeking placement to submit to a criminal history record check.
- (B) The criminal history record check shall be conducted not more than 90 days prior to placement of the applicant.
- (C) The cost of such inquiry shall be paid by either the home care placement agency or the individual seeking placement.

4.3 Disclosures

- (A) The placement agency shall provide a written disclosure notice to the consumer or authorized representative, before services are rendered, that specifies the service provided by the placement agency and the consumer's obligation regarding the home care worker.
- (B) The disclosure notice shall be signed by the consumer or authorized representative before the start of services and shall include information as to who is responsible for the following items:
 - (1) Employment of the home care worker,
 - (2) Liability for the home care worker while in the consumer's home,
 - (3) Payment of wages to the home care worker,
 - (4) Payment of employment and social security taxes,
 - (5) Payment of unemployment, workers' compensation general liability insurance, and, if provided, bond insurance,
 - (6) Supervision of the home care worker,
 - (7) Scheduling of the home care worker,
 - (8) Assignment of duties to the home care worker,
 - (9) Hiring, firing and discipline of the home care worker,
 - (10) Provision of material or supplies for the home care worker's use in providing services to the consumer, and

- (11) Training and ensuring qualifications that meet the needs of the consumer.

Section 5. DEPARTMENT OVERSIGHT

5.1 License classification

- (A) A home care agency shall be issued a license consistent with the type and extent of services provided. Unless otherwise specified, each agency shall meet the requirements in section 6 of this chapter as well as sections 7 and/or 8 depending upon the services provided.

Class A – a home care agency that provides any skilled healthcare service. Agencies with a Class A license may also provide personal care services.

Class B – a home care agency that provides only personal care services. An agency with a Class B license shall not provide any skilled healthcare service.

- (B) An agency providing home care services that are regulated by the Colorado Department of Health Care Policy and Financing (HCPF), excluding certified agencies defined in section 3.4 of this chapter, shall be licensed as a Class B agency unless otherwise specified below.

- (1) Any agency providing services regulated by HCPF or the department of human services that also provides skilled care or services delivered by a licensed professional shall be licensed as a class a agency.
- (a) In reviewing compliance with the requirements of this chapter by the Program of All-Inclusive Care for the Elderly (PACE) established in Section 25.5-5-412, C.R.S., the department shall coordinate with HCPF in regulatory interpretation of both license and certification requirements to ensure the intent of similar regulations is congruently met.
- (b) Any agency participating in the In-Home Support Service (IHSS) program administered by HCPF, shall be licensed as a Class B agency and shall comply with both HCPF's regulations concerning IHSS and the applicable portions of section 8 of this chapter. The department shall coordinate with HCPF in regulatory interpretation of both license and certification requirements to ensure the intent of similar regulations is congruently met.
- (2) If an agency's governing body, after consultation with the advisory committee, administrator or agency manager, determines a home care regulation substantially impedes its ability to provide appropriate and effective services to the consumer or substantially impedes the appropriate and effective services of the total program, the department may approve an alternate plan as long as the health, safety, welfare and rights of the consumer are assured.

(C) Residential facilities

- (1) Any residential facility that delivers skilled home health or personal care services that the facility is not licensed or certified to otherwise provide, shall either become licensed as a home care agency or require the skilled home health or personal care services to be delivered by a licensed home care agency.
 - (a) Consumer services shall be provided only upon individual service contracts. The resident or consumer requiring services not covered under the primary license shall be given the opportunity to contract with the home care agency of choice and shall not be restricted to the use of the residential facility home care agency.
 - (b) A residential facility may not contract for nor provide skilled home health or personal care services on a facility-wide basis under this license. Each residential facility providing facility-wide services shall be licensed according to the appropriate provider type.
 - (c) The home care records shall be easily identifiable and separated in the consumer record from the residential care records.
- (2) The requirements contained in sections 6 through 8 of this chapter shall apply only to processes, policies and procedures that address those consumers receiving skilled home health or personal care services in their temporary or permanent place of residence.
 - (a) The requirements apply to all residential facilities providing skilled home health services not covered under the primary residential care license or certification.
 - (b) The requirements for governing body, professional advisory committee, complaints, occurrences and quality assurance activities may be met, in whole or in part, in conjunction with like activities of the primary license. However, there shall be documented oversight of the home care portion of the services provided distinct from that of the primary license.

(D) Services provided to the developmentally disabled

- (1) On or after September 1, 2011, a community centered board that is directly providing home care services shall be licensed as either a Class A or B home care agency depending on the services being provided.
- (2) On or after September 1, 2011, a service agency that has received program approval from the Department of Human Services (DHS) as a developmental disabilities service agency under rules promulgated by DHS that is providing services pursuant to the supported living services waiver or the children's extensive support waiver shall be licensed as either a Class A or B home care agency depending on the services being provided.
- (3) Pursuant to Section 27-10.5-109(2), C.R.S., Independent Residential Support Services provided by the Colorado Department of Human Services (DHS) do not require licensure by the Department.

- (4) Nothing in this section relieves an entity that contracts or arranges with a community centered board or service agency, and that meets the definition of a "home care agency" under section 25-17.5-102, C.R.S., from the entity's obligation to apply for and operate under a license in accordance with these regulations.

5.2 License procedure

- (A) The HCA shall comply with the requirements of 6 CCR 1011-1, Chapter II, regarding license application procedures, the process for change of ownership and the continuing obligations of a licensee.
- (B) When submitting an application for an initial or renewal license, the HCA shall include evidence of either liability insurance coverage or a surety bond in lieu of liability insurance coverage. Such coverage shall be maintained for the duration of the license period. The minimum amount of coverage is:
 - (1) Class A – \$500,000 per occurrence and \$3,000,000 aggregate.
 - (2) Class B – \$100,000 per occurrence and \$300,000 aggregate.
- (C) The agency shall submit to the department a list of the contiguous counties that it plans to serve and assure adequate staffing, supervision, consumer care and services are provided within the declared geographical area.
- (D) Each HCA owner, applicant or licensee shall submit a complete set of his or her fingerprints to the department. The department shall forward such fingerprints to the Colorado Bureau of Investigation for the purpose of conducting a state and national fingerprint-based criminal history record check utilizing the records of the Colorado Bureau of Investigation and the Federal Bureau of Investigation. The owner, applicant or licensee shall pay the costs associated with the fingerprint-based criminal history record check to the Colorado Bureau of Investigation.
 - (1) No license shall be issued or renewed by the department if the owner, applicant, or licensee of the home care agency has been convicted of a felony or of a misdemeanor, which felony or misdemeanor involves moral turpitude or involves conduct that the department determines could pose a risk to the health, safety or welfare of HCA consumers.
 - (2) Each HCA owner, applicant or licensee is under an affirmative obligation to inform the department if he or she is convicted of a felony or of a misdemeanor that involves moral turpitude or conduct that the department determines could pose a risk to the health, safety or welfare of HCA consumers. Failure to advise the department of a conviction may result in non-renewal, or other appropriate sanctions, as set forth in sections 5.7, 5.8 and 5.9 of this chapter.
- (E) Except as otherwise specified herein, the department shall issue or renew a license when it is satisfied that the applicant or licensee is in compliance with these rules. A license issued or renewed pursuant to this section 5.2 shall expire one (1) year after the date of issuance or renewal.

- (F) No license shall be transferred from one location to another without prior notice to the department as provided in this subsection. If an agency is considering moving or changing the licensed physical address, the agency shall notify the department 30 days prior to the intended relocation.
 - (1) To retain the current license, the new physical location shall be relocated within the existing geographic service area and retain the same governing body and administrator.
 - (2) If the change in physical address does not meet the requirements listed above, the HCA shall submit an application for a new license.
- (G) The department may refuse to renew the license of a home care agency that is out of compliance with the requirements of Section 25-27.5-101, *et seq.*, C.R.S. or these rules.
- (H) If the department denies an application for an HCA initial or renewal license, the department shall notify the applicant in writing of such denial by mailing a notice to the applicant at the address shown on the application.
- (I) Any applicant believing himself or herself aggrieved by such denial may seek review of the decision if the applicant, within 60 days after receiving the written notice of denial, petitions the department to set a hearing.
- (J) All hearings on license denials shall be conducted in accordance with the state Administrative Procedure Act, Section 24-4-101, *et seq.*, C.R.S.

5.3 Provisional licenses

- (A) The department may issue a provisional license to any applicant for the purpose of operating a home care agency for a period of 90 days if the applicant is temporarily unable to conform to all of the minimum standards required by this chapter, except that no license shall be issued to an applicant if the operation of the applicant's home care agency will adversely affect the health, safety, or welfare of the home care consumers of such home care agency.
- (B) If requested by the Colorado Department of Health Care Policy and Financing, the department may issue a provisional license for a period of 90 days to an agency that has applied to be a certified home care agency as defined herein.
- (C) As a condition of obtaining a provisional license, the applicant shall show proof to the department that attempts are being made to conform and comply with applicable standards.
- (D) No provisional license shall be granted before completion of a criminal background check and finding in accordance with section 5.2 of this chapter.
- (E) A second provisional license may be issued, for a like term and fee, to effect compliance. No further provisional licenses may be issued for the current year after the second issuance.

5.4 License fees

- (A) Unless otherwise specified in this chapter, all license fees paid to the department shall be deemed non-refundable.
- (B) The appropriate fee total shall accompany an agency's initial or renewal license application. The fee total shall include any applicable branch and workstation fees as set forth in this section

5.4.1 Initial licensure

- (A) Each applicant for a home care agency license shall specify the type and extent of services to be provided and request the appropriate license category based upon the criteria set forth in section 5.1 of this chapter. The initial license fee shall be:

Class A - \$3,000

Class B - \$2,200

- (B) Any currently licensed Class B agency that desires to change its license category to a Class A agency shall submit an initial license application and initial license fee for a Class A license.

5.4.2 Provisional licensure

- (A) Any agency approved by the department for a provisional license, shall submit a fee equal to 15 percent of the applicable initial license fee for each provisional license term.
- (B) The appropriate fee shall be submitted before issuance of the provisional license.
- (C) If the department finds reasonable compliance by an applicant holding a provisional license, it shall issue an initial license upon receipt of the license application and total fee specified in sections 5.4 and 5.4.1 of this chapter.

5.4.3 Renewal licensure

- (A) Licenses with a renewal date prior to March1, 2012.

The renewal license fee shall be based upon the following chart. Reported wages shall be determined by utilizing all wages paid to direct home care staff on an annual basis and verified by the most recent workers' compensation insurance audit or Medicare cost report.

- (1) Any agency unable to submit a recent workers' compensation insurance audit shall submit an alternative form of wage verification as approved by the department.

Reported wages	Certified agency	Non-certified agency
Up to \$150,000	\$525	\$525
Greater than \$150,000	\$525 plus .10% of reported wages, not to exceed \$1,500	\$525 plus .15% of reported wages, not to exceed \$8,000

(B) Licenses with a renewal date effective on or after March 1, 2012.

The annual renewal license fee shall depend upon the type and volume of services, including consideration of Medicaid and Medicare services. The total renewal license fee shall include the appropriate base fee and, as applicable, additional volume fee; Medicaid or Medicare service discount; branch and workstation fees; and revisit fees.

(1) Base Fee

There shall be a base fee that is determined by the license category as defined in section 5.1 of this chapter. The renewal license base fee shall be:

Class A - \$1,550

Class B - \$1,325

(2) Additional volume fee

Each agency shall report its annual admissions for the previous year on its license renewal application. If the number of annual admissions is 50 or more, the agency shall add the following amount to its base fee:

50 to 99 admissions - \$100

100 or more admissions - \$200

(3) Medicare or Medicaid service discount

Each agency that is currently certified to provide Medicaid or Medicare services shall deduct \$100 from its base fee.

5.4.4 Branch and workstation fees

(A) In addition to any other licensure fees, the following fees shall apply to the circumstances described. The fees shall be submitted with the license application or as otherwise specified.

(1) An HCA shall submit a \$200 fee for each branch office as defined in section 3.2 of this chapter.

(a) For existing branches, the fee shall be submitted with the license application.

(b) For new branches, the fee shall accompany the notice of the agency's intent to open a branch office pursuant to section 6.2 of this chapter.

(2) An HCA that operates one or more satellite work stations solely for the convenience of direct care staff shall pay a fee of \$50 per workstation.

5.4.5 Revisit fee

- (A) An agency's annual license fee may be increased as the result of a licensure inspection or substantiated complaint investigation where a deficient practice is cited that has either caused harm or has the potential to cause harm to a consumer and the agency has failed to demonstrate appropriate correction of the cited deficiencies at the first on-site revisit.
- (B) The fee shall be 100 percent of the agency's initial or renewal license fee and shall be assessed for the second on-site inspection and each subsequent on-site inspection pertaining to the same deficiency.

5.4.6 Change of ownership fee

- (A) Any agency meeting the criteria set forth in 6 CCR 1011-1, Chapter II, section 2.7.2 shall pay a change of ownership fee. The fee shall be determined according to the license classifications set forth in section 5.1 of this chapter and submitted with the change of ownership notice. The fee shall be:

Class A - \$3,000

Class B - \$2,200

5.4.7 Change of name and change of address fees

- (A) A licensed HCA shall conform with the notification requirements of 6 CCR 1011-1, Chapter II, section 2.10.5 regarding any change in the agency name or business address.
- (B) A fee of \$75 shall accompany each notice of a change in agency name or business address.

5.5 Inspections

- (A) A certified home care agency that applies for a license by June 1, 2009, shall be exempt from licensure inspection prior to issuance of the initial license.
- (B) The department shall investigate and review each initial and renewal license application in order to determine an applicant's compliance with this chapter. This determination shall be based on one or more of the following:
 - (1) An on-site investigation of the agency;
 - (2) A review of the application and associated documents;
 - (3) A review of the agency's compliance history, including the results of complaint investigations;
 - (4) A review of occurrence reports;
 - (5) A review of material provided by the agency pursuant to a department request;
 - (6) Interviews of agency staff and/or consumers;

- (7) A review of information available from national accreditation organizations, CMS, HCPCF; and
 - (8) Any other information the department determines is appropriate to ascertain such compliance.
- (C) The department shall make such inspections as it deems necessary to ensure that the health, safety and welfare of home care consumers are being protected. In addition to licensure inspections, the department may conduct supplemental inspections at any time in response to complaints alleging noncompliance with the regulations contained in this chapter.
 - (1) Consumer records kept in the home or individual consumer documents not included in the HCA's permanent record shall be made available to the department within two hours of request if the last visit occurred 14 or more days prior to the request. The time for production may be extended at the department's discretion.
 - (2) The consumer file and administrative records including, but not limited to, census and demographic information, complaint and incident reports, meeting minutes, quality assurance and annual program review documents shall be provided to the inspector commencing within 30 minutes of request. The time for production may be extended at the department's discretion.
- (D) Inspections shall not be conducted in a home care consumer's home without the consumer's consent.
- (E) The HCA shall provide accurate and truthful information to the department during inspections, investigations and licensing activities. Failure to provide information requested by the department and known to the agency shall be grounds for action against a license.

5.6 Plan of correction

- (A) An HCA shall submit to the department a written plan of correction detailing measures that will be taken by the agency to correct deficiencies found as a result of inspections and shall be submitted in the form and manner required by the department.
- (B) Plans of correction shall be:
 - (1) Submitted within ten (10) calendar days after the date of the department's written notice of deficiencies, and
 - (2) Signed by the agency administrator.
- (C) Corrective actions shall be implemented within 45 days of the exit date or as determined by the department.
- (D) The department has the discretion to approve, modify or reject plans of correction.
 - (1) If the plan of correction is acceptable, the department shall notify the agency.
 - (2) If the plan of correction is unacceptable, the department shall notify the agency in writing and the agency shall re-submit changes to the department within the time frame specified by the department.

- (3) If the agency fails to comply with the requirements or deadlines for submission of a plan or fails to submit requested changes to the plan, the department may reject the plan of correction and impose intermediate restrictions or other disciplinary sanctions as set forth below.
- (4) If the agency fails to timely implement the actions agreed to in the plan of correction, the department may impose intermediate restrictions or other disciplinary sanctions as set forth below.

5.7 Intermediate restrictions or conditions

- (A) The department may impose intermediate restrictions or conditions on a license that may include at least one of the following:
 - (1) Retaining a consultant to address corrective measures;
 - (2) Monitoring by the department for a specific period;
 - (3) Providing additional training to employees, owners, or operators of the home care agency;
 - (4) Complying with a directed written plan to correct the violation, or
 - (5) Paying a civil fine not to exceed \$10,000 per calendar year for all violations.
- (B) If the department imposes an intermediate restriction or condition that is not the result of a serious and immediate threat to health or welfare, the department shall provide the agency with written notice of the restriction or condition. No later than ten (10) days after receipt of the notice, the agency shall submit a written plan that includes the time frame for completing the directed plan that addresses the restriction or condition specified.
- (C) If the department imposes an intermediate restriction or condition that is the result of a serious and immediate threat to health, safety or welfare, the department shall notify the agency in writing, by telephone, or in person during an on-site visit.
 - (1) The agency shall remedy the circumstances creating the harm or potential harm immediately upon receiving notice of the restriction or condition.
 - (2) If the department provides notice of a restriction or condition by telephone or in person, the department shall send written confirmation of the restriction or condition to the agency within two (2) business days.
- (D) After submission of an approved written plan, the agency may appeal any intermediate restriction or condition to the department through an informal review process as specified by the department.
- (E) If the department imposes an intermediate restriction or condition that requires payment of a civil fine, the agency may request and the department shall grant a stay in payment of the fine until final disposition of the restriction or condition.
- (F) If an agency is not satisfied with the result of the informal review or chooses not to seek informal review, no intermediate restriction or condition shall be imposed until after the opportunity for a hearing has been afforded the licensee pursuant to Section 24-4-105, C.R.S.

5.8 Revocation or suspension

- (A) The department may revoke or suspend the license of a home care agency that is out of compliance with the requirements of Section 25-27.5-101, *et seq.*, C.R.S. or these rules.
- (B) The department shall revoke or suspend the license of a home care agency where the owner or licensee has been convicted of a felony or misdemeanor involving moral turpitude or conduct that the department determines could pose a risk to the health, safety or welfare of the consumer of such agency.
- (C) Appeals of departmental revocations or suspensions shall be conducted in accordance with the state Administrative Procedure Act, Section 24-4-101, *et seq.*, C.R.S.

5.9 Summary suspension

- (A) The department may summarily suspend an agency's license if it finds, after investigation, that an agency has engaged in a deliberate and willful violation of these regulations or that the public health, safety, or welfare requires immediate action.
- (B) If the department summarily suspends an agency's license, it shall provide the agency with a notice explaining the basis for the summary suspension. The notice shall also inform the agency of its right to appeal and that it is entitled to a prompt hearing on the matter.
- (C) Appeals of summary suspensions shall be conducted in accordance with the state Administrative Procedure Act, Section 24-4-101, *et seq.*, C.R.S.

5.10 Civil fines

- (A) If the department assesses a civil fine pursuant to section 5.7 of this chapter, the money received by the department shall be transmitted to the state treasurer, who shall credit the same to the home care agency cash fund created in Section 25-27.5-105, C.R.S.
- (B) Civil fines collected pursuant to this section shall be used for expenses related to:
 - (1) Continuing monitoring required by this section,
 - (2) Education for agencies to avoid restrictions or conditions or facilitate the processes for application or change of ownership;
 - (3) Education for consumers and their families about resolving problems with an agency, rights of consumers and responsibilities of agencies;
 - (4) Providing technical assistance to any home care agency for the purpose of complying with changes in rules or state or federal law;
 - (5) Monitoring and assisting in the transition of consumers to other agencies, when the transition is the result of the revocation of a license, or other appropriate medical services; or
 - (6) Maintaining the operation of an agency pending correction of violations, as determined necessary by the department.

Section 6. GENERAL REQUIREMENTS FOR ALL LICENSE CATEGORIES

6.1 Out of state entities

Every HCA providing services within the state, shall have a physical business office capable of conducting day-to-day business as a home care agency within Colorado and shall be licensed according to the services rendered.

6.2 Branch offices

- (A) An HCA shall notify the department in advance of its plan to establish a branch office. Notification shall include:
 - (1) A description of the services to be provided,
 - (2) The geographic area to be served by the branch office, and
 - (3) A description of how the parent agency will supervise the branch office.
- (B) A branch office, as an extension of the parent HCA, may not offer services that are different than those offered by the parent HCA.
- (C) The parent agency administrator, manager or supervisor shall conduct an onsite visit of the branch office in accordance with agency policy.
- (D) One or more health professionals who possess the experience, education and qualifications to oversee all care and services provided by the branch shall be available during all operating hours.
 - (1) If only personal care services are provided, an employee that meets the qualifications of supervisor shall be available during all operating hours.
- (E) The location of the branch, in relation to the parent, shall be such that the parent is able to assure adequate supervision at all times.
- (F) The branch office shall have a copy of all agency policies available and readily accessible to staff.
- (G) The agency shall ensure that consumer records are readily accessible to all staff providing care and services.

6.3 Criminal history record checks

- (A) On or after June 1, 2009, the HCA shall require any individual seeking employment with the agency to submit to a criminal history record check.
- (B) The criminal history record check shall be conducted not more than 90 days prior to employment of the individual.
- (C) The cost of such inquiry shall be paid by either the home care agency or the individual seeking employment.
- (D) The HCA shall develop and implement policies and procedures regarding the employment of any individual who is convicted of a felony or misdemeanor to ensure that the individual does not pose a risk to the health, safety and welfare of the consumer.

6.4 Consumer rights

(A) Assurance of rights

- (1) The HCA shall establish and implement written policies and procedures regarding the rights of consumers and the implementation of these rights. A complete statement of these rights, including the right to file a complaint with the department, shall be distributed to all employees and contracted personnel upon hire.
- (2) At a minimum, the HCA's policies and procedures shall specify that:
 - (a) The consumer or authorized representative has the right to be informed of the consumer's rights through an effective means of communication.
 - (b) The consumer has the right to be assured that the HCA shall not condition the provision of care or otherwise discriminate against a consumer based upon personal, cultural or ethnic preference, disabilities or whether the consumer has an advance directive.
 - (c) The HCA shall protect and promote the exercise of these rights.

(B) Notice of rights

- (1) Within one (1) business day of the start of services, the HCA shall provide the consumer or authorized representative with a notice of the consumer's rights in a manner that the consumer understands. The notice shall include information about the consumer's options if rights are violated, including how to contact an individual employed with the HCA who is responsible for the complaint intake and problem resolution process.

(C) Exercise of rights and respect for property and person

- (1) The rights of the consumer may be exercised by the consumer or authorized representative without fear of retribution or retaliation.
- (2) The consumer has the right to have his or her person and property treated with respect. The consumer has the right to be free from neglect, financial exploitation, verbal, physical and psychological abuse including humiliation, intimidation or punishment.
- (3) The consumer or authorized representative, upon request to the HCA, has the right to be informed of the full name, licensure status, staff position and employer of all persons with whom the consumer has contact and who is supplying, staffing or supervising care or services. The consumer has the right to be served by agency staff that is properly trained and competent to perform their duties.
- (4) The consumer has the right to live free from involuntary confinement, and to be free from physical or chemical restraints as defined in 6 CCR 1011-1, Chapter II, Part 8.
- (5) The consumer or authorized representative has the right to express complaints verbally or in writing about services or care that is or is not furnished, or about the lack of respect for the consumer's person or property by anyone who is furnishing services on behalf of the HCA.

- (6) The consumer shall have the right to confidentiality of all records, communications, and personal information. The HCA shall advise the consumer of the agency's policies and procedures regarding disclosure of clinical information and records.
- (D) Right to be informed and to participate in planning care and services
 - (1) The HCA shall inform the consumer or authorized representative in advance about the care and services to be furnished, and of any changes in the care and services to be furnished to enable the consumer to give informed consent.
 - (a) The consumer has the right to refuse treatment within the confines of the law, to be informed of the consequences of such action and to be involved in experimental research only upon the consumer's voluntary written consent.
 - (b) The consumer has the right to be told in advance of receiving care about the services that will be provided, the disciplines that will be utilized to furnish care, the frequency of visits proposed to be furnished and the consequences of refusing care or services.
 - (2) The HCA shall offer the consumer or authorized representative the right to participate in developing the plan of care and receive instruction and education regarding the plan.
 - (a) The HCA shall advise the consumer in advance of the right to participate in planning the care or treatment, and in planning changes in the care or treatment
 - (b) Within one (1) business day of the start of services, the HCA shall inform the consumer concerning the agency's policies on advance directives, including a description of applicable state law. The HCA may furnish advance directives information to a consumer at the time of the first home visit, as long as the information is furnished before care is provided.
- (E) The consumer or authorized representative has the right to be advised orally and in writing within one (1) business day of the start of services of the extent to which payment for the HCA services may be expected from insurance or other sources, and the extent to which payment may be required from the consumer.
- (F) The consumer or authorized representative has the right to be advised of any changes in billing or payment procedures before implementation.
 - (1) If an agency is implementing a scheduled rate increase to all clients, the agency shall provide a written notice to each affected consumer at least 30 days before implementation.
 - (2) The HCA shall advise the consumer of any individual changes orally and in writing as soon as possible, but no later than five (5) business days from the date that the HCA becomes aware of a change.

- (3) An HCA shall not assume power of attorney or guardianship over a consumer utilizing the services of the HCA, require a consumer to endorse checks over to the HCA or require a consumer to execute or assign a loan, advance, financial interest, mortgage or other property in exchange for future services.
- (G) The consumer or authorized representative has the right to be advised of the availability of the state's toll-free HCA hotline. When the agency accepts the consumer for treatment or care, the HCA shall advise the consumer in writing of the telephone number of the home health hotline established by the state, the hours of its operation and that the purpose of the hotline is to receive complaints or questions about local HCAs. The consumer also has the right to use this hotline to lodge complaints regarding care received or not received including implementation of the advance directives requirements.
- (H) The HCA shall make available to the consumer or authorized representative, upon request, a written notice listing all individuals or other legal entities having ownership or controlling interest in the agency.
- (I) The HCA shall maintain documentation showing that it has complied with the requirements of this section.

6.5 Admissions

- (A) Agencies shall only accept consumers for care or services on the basis of a reasonable assurance that the needs of the consumer can be met adequately by the agency in the individual's temporary or permanent home or place of residence.
 - (1) There shall be initial documentation of the agreed upon days and times of services to be provided based upon the consumer's needs that is updated at least annually.
- (B) If an agency receives a referral of a consumer who requires care or services that are not available at the time of referral, the agency shall advise the consumer's primary care provider, if applicable, and the consumer or authorized representative of that fact.
 - (1) The agency shall only admit the consumer if the primary care provider and the consumer or consumer's representative agree the ordered services can be delayed or discontinued.

6.6 Discharge planning

- (A) There shall be a specific plan for discharge in the consumer record and there shall be ongoing discharge planning with the consumer.
- (B) If no improvement or no discharge is expected, the agency shall document in the consumer record this assessment.
- (C) The HCA shall assist each consumer or authorized representative to find an appropriate placement with another agency if the consumer continues to require care and/or services upon discharge. The HCA shall document due diligence in ensuring continuity of care upon discharge as necessary to protect the consumer's safety and welfare.

- (D) Once admitted, an HCA shall not discontinue or refuse services to a consumer unless documented efforts have been made to resolve the situation that triggered such discontinuation or refusal to provide services.

- (1) The consumer or authorized representative shall be notified verbally and in writing of the agency's intent to discharge and the reasons for the discharge.

6.7 Disclosure notice

- (A) The HCA shall provide a written disclosure notice to the consumer or authorized representative within one (1) business day of the start of services that specifies the service provided by the HCA and the consumer's obligation regarding the home care worker.
- (B) The disclosure notice shall be signed by the consumer or authorized representative and shall include information as to who is responsible for the following items:
 - (1) Employment of the home care worker,
 - (2) Liability for the home care worker while in the consumer's home,
 - (3) Payment of wages to the home care worker,
 - (4) Payment of employment and social security taxes,
 - (5) Payment of unemployment, worker's compensation, general liability insurance, and, if provided, bond insurance.
 - (6) Supervision of the home care worker,
 - (7) Scheduling of the home care worker,
 - (8) Assignment of duties to the home care worker,
 - (9) Hiring, firing and discipline of the home care worker,
 - (10) Provision of materials or supplies for the home care worker's use in providing services to the consumer, and
 - (11) Training and ensuring qualifications that meet the needs of the consumer.
- (C) The HCA shall ensure that the consumer or authorized representative acknowledges the disclosure notice is within one (1) business day of the start of services.

6.8 Non-compete agreements

- (A) An HCA shall not coerce, threaten, or use any means of intimidation to prevent an employee from terminating the employment relationship and commencing employment at another HCA.
- (B) Non-compete clauses, agreements or contracts shall only be enforceable in accordance with Section 8-2-113, C.R.S.

6.9 Complaint processing

- (A) The HCA shall develop and implement policies to include the following items:
 - (1) Investigation of complaints made by a consumer or others about services or care that is or is not furnished, or about the lack of respect for the consumer's person or property by anyone furnishing services on behalf of the HCA.
 - (2) Documentation of the existence, the investigation and the resolution of the complaint. The agency shall notify the complainant of the results of the investigation and the agency's plan to resolve any issue identified.
 - (3) Incorporation of the substantiated findings into its quality assurance program in order to evaluate and implement systemic changes where needed.
 - (4) Explicit statement that the HCA does not discriminate or retaliate against a consumer for expressing a complaint or multiple complaints.
 - (5) Maintenance of a separate record/log/file detailing all activity regarding complaints received, and their investigation and resolution thereof. The record shall be maintained for at least a two (2) year period of time and shall be available for audit and inspection purposes.

6.10 Agency reporting requirements

- (A) Each HCA shall comply with the occurrence reporting requirements set forth in 6 CCR 1011, Chapter II, section 3.2.
- (B) The agency shall investigate each reportable occurrence and institute appropriate measures to prevent similar future occurrences.
 - (1) Documentation regarding the investigation, including the appropriate measures to be instituted, shall be made available to the department, upon request.
 - (2) A report with the investigation findings shall be available for review by the department within five (5) working days of the occurrence.
- (C) Nothing in this section 6.10 shall be construed to limit or modify any statutory or common-law right, privilege, confidentiality or immunity.
- (D) An HCA shall notify the department before it initiates discharge of any consumer who requires and desires continuing paid care or services where there are no known transfer arrangements to protect the consumer's health, safety or welfare.
 - (1) Emergency discharges necessary to protect the safety and welfare of staff shall be reported to the department within 48 hours of the occurrence.

- (E) The home care agency shall ensure that all staff have knowledge of Article 3.1 of Title 26, C.R.S. regarding protective services for at-risk adults, and that all incidents involving neglect, abuse or financial exploitation are reported immediately, through established procedures, to the agency administrator or manager.
 - (1) Any home care agency that provides care and/or services to pediatric consumers, shall ensure that all staff have knowledge of Part 3 of Article 3 of Title 19, C.R.S. regarding child abuse or neglect, and that all incidents involving child abuse or neglect are reported immediately, through established procedures, to the agency administrator or manager.
 - (2) The agency shall report the incident to the appropriate officials as specified in the statute and, if applicable, to the department as an occurrence. The agency shall make copies of all such reports available to the department upon request.
 - (3) The agency shall document that all alleged incidents involving neglect, abuse or health professional misconduct are thoroughly investigated in a timely manner. The agency shall develop and implement a policy that addresses what administrative procedures will be implemented to protect its consumers during the investigation process.

6.11 Personnel records and policies

- (A) Agency policy shall direct any program or service offered by the HCA directly or under arrangement is provided in accordance with the plan of care and agency policy and procedure.
 - (1) The HCA shall define the required competence, qualifications, and experience of staff in each program or service it provides.
 - (2) Personnel policies shall be available to all full and part-time employees.
- (B) Personnel records for all employees shall include references, dates of employment and separation from the agency, and the reason for separation. Personnel records for all employees shall also include:
 - (1) Qualifications and licensure that are kept current.
 - (a) Qualifications include confirmation of type and depth of experience, advanced skills, training and education; and appropriate, detailed and observed competency evaluation and written testing overseen by a person with the same or higher validated qualifications.
 - (2) Orientation to the agency,
 - (3) Job descriptions for all positions assigned by the agency, and
 - (4) Annual performance evaluation for each employee.
- (C) Before employing any individual to provide direct consumer care or services, the agency shall contact the Colorado Department of Regulatory Agencies (DORA) to verify whether a license, registration or certification exists and is in good standing. a copy of the inquiry shall be placed in the individual's personnel file.

6.12 Emergency preparedness

- (A) The home care agency (HCA) shall have a written emergency preparedness plan that is designed to manage consumers' care and services in response to the consequences of natural disasters or other emergencies that disrupt the agency's ability to provide care and services or threatens the lives or safety of its consumers.
- (B) At a minimum, an agency's written emergency preparedness plan shall include the following:
 - (1) Provisions for the management of all staff who are designated to be involved in emergency measures, including the assignment of responsibilities and functions. All staff shall be informed of their duties and be responsible for implementing the emergency preparedness plan.
 - (2) Education for consumers, caregivers and families on how to handle care and treatment, safety and/or well-being during and following instances of natural (tornado, flood, blizzard, fire, etc.) and other disasters or other similar situations appropriate to the needs of the consumer.
 - (3) Adequate staff education on emergency preparedness so that staff safety is assured.
- (C) The agency shall review its emergency preparedness plan after any incident response and on an annual basis, and incorporate into policy any substantive changes.

6.13 Coordination with external home care agencies

- (A) Each HCA shall be responsible for the coordination of consumer services with known external HCAs providing care and services to the same consumer.
 - (1) No HCA shall refuse to share consumer care information unless the consumer has chosen to refuse coordination with external HCAs.
 - (2) The consumer's refusal of such coordination shall be documented in the consumer's record.

6.14 Quality management program

- (A) Every HCA shall establish a quality management program appropriate to the size and type of agency that evaluates the quality of consumer services, care and safety, and that complies with the requirements set forth in 6 CCR 1011, Chapter II, section 3.1.

6.15 Infection control

- (A) The HCA shall provide training for its employees regarding the agency's written infection control policies and procedures at the time of hire and annually.
- (B) The HCA shall evaluate the adequacy of its infection control policies and procedures at least annually, make any necessary substantive changes, and document in writing.

6.16 Employee health – communicable disease prevention

- (A) It shall be the responsibility of the HCA to establish written policies concerning pre-employment physical evaluations and employee health. Those policies shall include, but not be limited, to:
 - (1) Work restrictions to be placed on direct care staff who are known to be affected with any illness in a communicable stage or to be a carrier of a communicable illness or disease; afflicted with boils, jaundice, infected wounds, vomiting, diarrhea or acute respiratory infections.

6.17 Missed visits

- (A) There shall be a mechanism for informing the consumer about scheduled visits in accordance with agency policy. Documentation shall be maintained and alterations in the schedule shall be provided to the consumer as soon as practical.
 - (1) The HCA's policy shall address processes for HCA planning for coverage of employee illness, vacation, holidays and unexpected voluntary or involuntary termination of employment.
 - (2) If the consumer does not respond to let staff in the home for the scheduled visit, the HCA's attempts to ensure the safety of the consumer and the outcome of each attempt shall be documented.
 - (3) If there is a missed visit, services shall be provided as agreed upon by the consumer and the HCA.
 - (4) If the HCA admits consumers with needs that require care or services to be delivered at specific times or parts of day, the HCA shall ensure qualified staff in sufficient quantity are employed by the agency or have other effective back-up plans to ensure the needs of the consumer is met.
 - (5) The back-up plan for scheduled visits shall not include calling for an ambulance or other emergency services unless the presence of the scheduled staff in the home would still have warranted the summons of emergency services.

6.18 Contracts

- (A) If personnel under hourly or per visit contracts are used by the HCA, there shall be a written employment contract between those personnel and the agency that specifies the following:
 - (1) Home care consumers are accepted for care only by the primary HCA,
 - (2) The specific services to be furnished,
 - (3) The necessity to conform to all applicable agency policies, including personnel qualifications,
 - (4) The responsibility for participating in developing plans of care or service,
 - (5) The manner in which services will be controlled, coordinated, and evaluated by the primary HCA,

- (6) The procedures for submitting clinical/service notes, scheduling of visits, periodic consumer evaluation, and
- (7) The procedures for payment for services furnished under the contract.

6.19 Information management system

- (A) Each HCA shall implement a policy and procedure for an effective information management system either paper-based or electronic. Processes shall include effective management for capturing, reporting, processing, storing and retrieving clinical/service data and information in accordance with standards of practice. The system shall provide for:
 - (1) Privacy and confidentiality of protected health information from unauthorized use or manipulation;
 - (2) Organization of the consumer record utilizing standardized formats for documenting all care, treatment and services provided to consumers according to agency policy. Standardization shall not include pre-filled documentation of future care and services.
- (B) In addition, for electronic consumer healthcare records, policies and procedures shall be devised and implemented to ensure:
 - (1) A method for validating data entry access and changes to previously entered data, and
 - (2) Recovery of records including contingency plans for operational interruptions (hardware, software, or other systems failures), emergency service plan, a back-up system for retrieval of data from storage and information presently in the operating system.

6.20 Consumer record content

- (A) All HCAs shall have a complete and accurate record for each consumer assessed, cared for, treated or served. The record shall contain sufficient information to identify the consumer; support the diagnosis or condition; justify the care, treatment, and/or services delivered; and promote continuity of care internally and externally, where applicable.
 - (1) Such records shall contain consumer-specific information as appropriate to the care, treatment or services provided including but not limited to:
 - (a) Records of communications with the consumer or authorized representative regarding care, treatment and services, including documentation of phone calls and e-mails, and
 - (b) Referrals to and names of known home care agencies, individuals and organizations involved in the consumer's care

- (2) Clinical records for HCAs providing skilled home health services shall contain, where applicable:
 - (a) Hospital and emergency room records for known episodes or documentation of efforts to obtain the information,
 - (b) Medical equipment provided by the HCA or related to the care, treatment and services provided including assessment of consumer and family comprehension of appropriate use and maintenance,
 - (c) Consumer and family education, and training on services or treatments and the use of equipment at the time of delivery to the home,
 - (d) Safety measures taken to protect the consumer from harm including fall risk assessments, and documentation why any identified or planned safety measures were not implemented or continued, and
 - (e) Diagnostic and therapeutic procedures, treatments, tests and their results where known to have occurred.

Section 7. SKILLED CARE

7.1 Governing body

- (A) A home care agency shall have an organized governing body.
 - (1) The body shall consist of members who singularly or collectively have business and healthcare experience sufficient to oversee the services provided by the home care agency.
- (B) The governing body shall have a process for review of agency operations at least quarterly and meet at least annually.
- (C) The governing body shall assume responsibility for:
 - (1) Compliance with all federal regulations, state rules, and local laws;
 - (2) Quality consumer care;
 - (3) Policies and procedures which describe and direct functions or services of the home care agency and protect consumer rights;
 - (4) Bylaws that shall include, at a minimum:
 - (a) A description of functions and duties of the governing body, officers, and committees;
 - (b) A statement of the authority and responsibility delegated to the administrator;
 - (c) Meet as stated in bylaws, at least annually;
 - (d) Appoint in writing a qualified administrator who is responsible for the agency's overall functions.

- (5) Review of the written agency evaluation report and other communications from the administrator or group of professional personnel with evidence of written response;
- (6) Establish and ensure the maintenance of a system of financial management and accountability; and
- (7) Organization, services furnished, administrative control and lines of authority for the delegation of responsibility down to the consumer care level that are clearly set forth in writing and are readily identifiable.

7.2 Administration

- (A) The HCA, under the direction of the governing body, shall be responsible for preparation of an overall plan and a budget that includes an annual operating budget and capital expenditure plan, as applicable.
 - (1) The overall plan and budget shall be prepared by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HCA. The overall plan and budget shall be reviewed and updated at least annually by the committee referred to herein under the direction of the HCA governing body.
- (B) Any HCA that performs procedures in the consumer's residence that are considered waived clinical laboratory procedures under the Clinical Laboratory Improvement Act of 1988, shall possess a certificate of waiver from the Centers for Medicare and Medicaid Services or its designated agency.
- (C) Any HCA that provides equipment to consumers shall have written policies and procedures for the management of medical equipment provided for use in consumer homes including selection, acquisition, delivery and maintenance of the equipment.
 - (1) The HCA shall make full disclosure of the policies and procedures to all consumers before the equipment is provided. The policies and procedures shall include the following:
 - (a) A process to provide an appropriate back-up system including emergency services 24 hours per day where the malfunction may threaten the consumer's life;
 - (b) Monitoring and acting upon equipment hazard notices and recalls;
 - (c) Checking equipment upon delivery to the consumer to ensure it is sanitary, undamaged and operating properly;
 - (d) Basic safety and operational checks on infusion pumps that include a volumetric test of accuracy of infusion rate between each consumer use; and
 - (e) Performance of routine and preventative maintenance conducted at defined intervals per manufacturer's guidelines.

- (E) Availability
 - (1) The agency shall have a registered nurse or other appropriate health professional available after business hours.
 - (2) The agency shall have a policy describing, at a minimum, the following:
 - (A) How consumers will contact the agency after hours; and
 - (B) How the agency will ensure the health professional on call has access to all current consumer information.

7.3 Professional advisory committee

- (A) Each HCA shall have a group of professional personnel that includes at least one physician and one registered nurse, an appropriate representation from the professional disciplines the HCA employs or contracts with to provide services.
 - (1) The group of professional personnel shall establish and annually review the agency's policies governing the services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications and program evaluation.
 - (2) At least one member of the group shall not be an owner, an employee or a contractor for the provision of consumer care services for the HCA.
- (B) The agency shall implement an on-going mechanism for consumer involvement to provide input and comment regarding services provided by the agency in accordance with agency policy. Consumer input and commentary shall be provided to the group of professional personnel at least annually to identify trends or issues requiring consideration of the group.
- (C) The group of professional personnel shall meet annually and as frequently as necessary to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program.
 - (1) The HCA shall have a policy and procedure to establish criteria for calling a meeting of the group of professional personnel more frequently than annually. The policy shall be developed to ensure professional advice is requested and received at an appropriate frequency to protect and preserve the health, safety and welfare of the consumers it serves.
 - (2) Each meeting shall be documented with the date and the signatures of attendees. Meeting minutes shall be forwarded to the governing body to review and make recommendations.

7.4 Agency evaluation

- (A) The agency's governing body or its designee shall conduct a comprehensive evaluation of the agency's total operation at least annually.
- (B) The evaluation shall assure the appropriateness and quality of the agency's services with findings used to verify policy implementation, to identify problems, and to establish problem resolution and policy revision as necessary.

- (C) The evaluation shall consist of an overall policy and administration review, including the scope of services offered, arrangements for services with other agencies or individuals, admission and discharge policies, supervision and plan of care, emergency care, service records and personnel qualifications.
- (D) In evaluating each aspect of its total program, the HCA shall consider four main criteria:
 - (1) Appropriateness - assurance that the area being evaluated addresses existing and/or potential problems.
 - (2) Adequacy - a determination as to whether the HCA has the capacity to overcome or minimize existing or potential problems.
 - (3) Effectiveness - the services offered accomplish the objectives of the HCA and anticipated consumer outcomes.
 - (4) Efficiency - whether there is a minimal expenditure of resources by the HCA to achieve desired goals and anticipated consumer outcomes.
- (E) Documentation of the annual evaluation shall include the names and titles of the persons carrying out the evaluation, the criteria and methods used to accomplish it and any action taken by the agency as a result of its findings.
- (F) Appropriate professionals representing the scope of the agency's program shall evaluate the agency's client records at least quarterly.
 - (1) The evaluation shall include a review of sample active and closed client records to ensure that agency policies are followed in providing services, both direct and under arrangement, and to assure that the quality of service is satisfactory and appropriate. The review shall consist of a representative sample of all home care services provided by the agency.

7.5 Administrator

- (A) The administrator shall assume authority for the operation of the agency's skilled health services including but not limited to:
 - (1) Organizing and directing the agency's ongoing functions;
 - (2) Employing qualified personnel and ensure appropriate ongoing education and supervision of personnel and volunteers;
 - (3) Ensuring the accuracy of public information materials and activities;
 - (4) Implementing a budgeting and accounting system; and
 - (5) Designating a qualified alternate administrator to act in the administrator's absence.
- (B) The administrator shall:
 - (1) Be at least 21 years of age,
 - (2) Be a licensed physician, registered nurse or other licensed healthcare professional, or have experience and education in health service administration,

- (3) Be qualified by education, knowledge and experience to oversee the services provided, and
 - (4) Have at least two years healthcare or health service administration experience with at least one year of supervisory experience in home care or a closely related health program.
- (C) The administrator shall have the overall responsibility to ensure the following:
 - (1) The agency's skilled health services are in compliance with all applicable federal, state and local laws,
 - (2) The completion, maintenance and submission of such reports and records as required by the department,
 - (3) Ongoing liaison with the governing body, staff members and the community,
 - (4) A current organizational chart to show lines of authority down to the consumer level,
 - (5) The management of the business affairs and the overall operation of the agency,
 - (6) Maintenance of appropriate personnel records, financial and administrative records and all policies and procedures of the agency,
 - (7) Employment of qualified personnel in accordance with written job descriptions,
 - (8) Orientation of new staff, regularly scheduled in-service education programs and opportunities for continuing education for the staff,
 - (9) Designate in writing the qualified staff member to act in the absence of the administrator, and
 - (10) Availability of the administrator or designee at all hours employees are providing services, at minimum, any eight (8) hour period between 7 a.m. and 7 p.m. Monday through Friday.
 - (11) Marketing, advertising and promotional information accurately represents the HCA and addresses the care, treatment and services that the HCA can provide directly or through contractual arrangement.

7.6 Curriculum for administrator training

- (A) A first-time administrator or alternate administrator shall complete a total of 24 hours of training in the administration of an agency before the end of the first 12 months after designation to the position.
- (B) A first-time administrator or alternate administrator shall complete eight (8) clock hours of educational training in the administration of an agency within the first month of employment. The eight (8) clock hours shall include, at a minimum, the following topics:
 - (1) Home care overview,
 - (2) Information on the licensing standards for the agency; and

- (3) Information on state and local laws applicable to the agency.
- (C) A first-time administrator or alternate administrator shall 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 16 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 shall include the following subjects and may include other topics related to the duties of an administrator:
 - (1) Consumer rights, governing body and administrator responsibilities, professional advisory committee, quality management plans, occurrence reporting, and complaint investigation and resolution process,
 - (2) Personnel qualifications, experience, competency and evaluations,
 - (3) Financial management,
 - (4) Ethics in healthcare,
 - (5) Needs of the fragile, ill and physically and cognitively disabled in the community setting with special training and staffing considerations,
 - (6) Behavior management techniques,
 - (7) Staffing methodologies and oversight of scheduling,
 - (8) Staff training and supervision, and
 - (9) Limitations of personal care versus health care services.
- (D) The 24-hour education requirement shall be met through structured, formalized classes, correspondence courses, competency-based computer courses, training videos, distance learning programs, or other training courses. Subject matter that deals with the internal affairs of an organization does not qualify for credit. The training shall be provided or produced by an academic institution, a recognized state or national organization or association, an independent contractor, or an agency.
 - (1) If an agency or independent contractor provides or produces training, the training shall first be approved by the department or recognized by a national organization or association. The agency shall maintain documentation of this approval for review by inspectors.
- (E) Documentation of administrator or alternate administrator training must be on file at the agency and contain the name of the class or workshop, the course content or curriculum, the hours and dates of the training, and the name and contact information of the entity and trainer who provided the training.
- (F) After completion of the 24 hours of educational training within the first 12 months after designation as a first-time administrator or alternate administrator, each must then complete the continuing education requirements in each subsequent 12-month period after designation.

- (G) An administrator shall complete 12 clock hours of continuing education within each 12-month period beginning with the date of designation. The education shall include at least two (2) of the following topics and may include other topics related to the duties of the administrator.
- (1) Any of the topics listed under the initial training requirements,
 - (2) Development and implementation of agency policies,
 - (3) Healthcare management,
 - (4) Ethics,
 - (5) Quality improvement,
 - (6) Risk assessment and management,
 - (7) Financial management,
 - (8) Skills for working with consumers, families and other professional service providers,
 - (9) Community resources,
 - (10) Marketing.
- (H) For an administrator or alternate administrator who was an administrator prior to June 1, 2009, but had not served as an administrator for 180 days or more immediately preceding the date of designation, at least eight (8) of the 12 clock hours within the first 12 months after designation shall include the topics listed for first time administrators. The remaining four clock hours shall include topics related to the duties of the administrator and include at least two (2) of the topics listed under continuing education. If a previous administrator has not been employed as such for two (2) years or more, the requirements for a first time administrator apply.

7.7 Nursing or healthcare supervisor

- (A) The skilled nursing services furnished shall be under the supervision and direction of a physician or registered nurse who has at least two (2) years of nursing experience including one (1) year in home care or a closely related service. Other healthcare services shall be under the supervision and direction of a physician, registered nurse, or other licensed healthcare professional who has at least two (2) years healthcare experience in the field of supervision including one year experience in home care or a closely related service.
- (B) This person, or similarly qualified alternate, shall be available at all times during operating hours and participate in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

7.8 Personnel

- (A) Each employee and contracted staff shall possess the education and experience to provide services in the homes of consumers in accordance with agency policy, state practice acts and professional standards of practice as set forth in this chapter.

- (B) Licensed, registered or certified healthcare providers shall, at a minimum, meet the following requirements:
 - (1) Be qualified as a physician, pharmacist, physician assistant, nurse practitioner, clinical social worker, social worker, physical therapist, occupational therapist, respiratory therapist, registered nurse, licensed practical nurse, massage therapist, certified nurse aide or other provider licensed, registered or certified by the Colorado Department of Regulatory Agencies (DORA).
 - (2) Meet the requirements for license, certification or registration set forth by DORA.
- (C) Staff not regulated under DORA shall, at a minimum, meet the following requirements.
 - (1) A speech-language pathologist shall:
 - (a) Possess a current certificate of clinical competence in speech pathology or audiology granted by the American Speech-Language-Hearing Association, or
 - (b) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.
 - (2) An occupational therapy assistant shall, at a minimum:
 - (a) Possess a current certification from the National Board for Certification of Occupational Therapy (NBOT).
 - (3) A physical therapist assistant shall:
 - (a) Have completed a physical therapist assistant program accredited by the commission on accreditation in physical therapy or any comparable successor entity;
 - (b) Be registered, licensed or certified as a physical therapist assistant in another state; or
 - (c) Be otherwise qualified to take the physical therapy examination.
 - (4) An X-ray technician shall:
 - (a) Have successfully completed a program of formal training in X-ray technology of not less than 24 months in a school approved by the Committee on Allied Health Education and Accreditation of the American Medical Association or by the American Osteopathic Association; or
 - (b) Have earned a bachelor's or associate degree in radiological technology from an accredited college or university.
 - (5) A phlebotomist shall:
 - (a) Have successfully completed an approved phlebotomy training course or equivalent experience through previous employment; and
 - (b) Have two (2) years of verifiable phlebotomy experience.

- (D) Ongoing training shall be provided to all direct care staff. Training requirements shall be consistent with the program, services and equipment it provides and are appropriate to the needs of the populations served.
 - (1) Training shall consist of at least 12 topics applicable to the agency's care and services every 12 months after the starting date of employment or calendar year as designated by agency policy. The training requirement shall be prorated in accordance with the number of months the employee was actively working for the agency. Training shall include, but is not limited to, the following items:
 - (a) Promoting consumer dignity, independence, self-determination, privacy, choice and rights; including abuse and neglect prevention and reporting requirements;
 - (b) Behavior management techniques;
 - (c) Disaster and emergency procedures; and
 - (d) Infection control including universal precautions.
 - (2) All training shall be documented. Classroom type trainings shall be documented with the date of the training; starting and ending times; instructors and their qualifications; short description of content; and staff member's signature. On-line or self-study trainings shall be documented with information as to the content of the training, and the entity that offered or produced the training.

7.9 Initial and comprehensive assessments

- (A) Initial assessment visit
 - (1) A registered nurse shall conduct an initial assessment visit to determine the immediate care and support needs of the consumer. The initial assessment visit shall be held either within 48 hours of referral, or within 48 hours of the consumer's return home, or on the attending provider-ordered start-of-care date.
 - (2) When an alternate professional healthcare service is the only service ordered, the initial assessment visit may be made by the appropriate skilled healthcare professional.
- (B) Comprehensive assessment of consumers
 - (1) The HCA shall accomplish an individualized comprehensive assessment that accurately reflects each consumer's current health status and includes information that may be used to demonstrate the consumer's progress toward achievement of the desired outcomes.
 - (2) The comprehensive assessment shall identify the consumer's need for home care and meet the consumer's medical, nursing, rehabilitative, social and discharge planning needs.
 - (3) The comprehensive assessment shall be completed in a timely manner, consistent with the consumer's immediate needs, but no later than five (5) calendar days after the start of care.

- (4) Except as otherwise indicated in this section, a registered nurse shall complete the comprehensive assessment.
- (5) When healthcare services other than nursing are ordered by the physician, the primary professional healthcare worker shall complete the comprehensive assessment.
- (6) The comprehensive assessment shall include a review of all medications the consumer is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy and noncompliance with drug therapy.
 - (a) The HCA shall report any concerns to the attending physician, and the director of nursing and these reports shall be acted upon.
- (7) The comprehensive assessment shall be updated and revised as frequently as the consumer's condition warrants due to a major decline or improvement in the consumer's health status. At a minimum, it shall be updated and revised:
 - (a) Every 60 days beginning with the start-of-care date; and
 - (b) Within 48 hours of the consumer's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests or, for non-certified agencies, as ordered by the physician or intermediate care provider.
- (C) Provision of skilled services
 - (1) The HCA shall have written policies regarding nurse delegation. The policy shall delineate what tasks or procedures may or may not be delegated, the delegation process, documentation and how the delegate shall be supervised in accordance with state regulation. If the HCA prohibits delegation, there shall be a policy that specifies such prohibition.

7.10 Plan of care

- (A) Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine. Care plans established by a nurse practitioner or physician assistant may be accepted by an HCA that is not federally certified as a home care agency. For PACE participants, the interdisciplinary team shall establish, follow and periodically review the plan of care.
 - (1) The plan of care shall be developed in consultation with the agency staff and covers all pertinent diagnoses, including mental status, types of services, identification of any services furnished by other providers and how those services are coordinated, equipment required, frequency and duration of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, instructions for timely discharge or referral and any other appropriate items.
 - (a) The plan of care shall identify the consumer's continuing need for home care and meet the consumer's medical, nursing, rehabilitative, social and discharge planning needs.

- (b) The plan of care reflects the participation of the consumer to the extent possible. The HCA communicates the plan of care to the consumer/caregiver in a comprehensible way.
- (B) If a physician or intermediate care provider refers a consumer under a plan of care that cannot be completed until after an evaluation visit, the attending physician or attending intermediate care provider shall be consulted to approve additions or modifications to the original plan. Orders for therapy services shall include the specific procedures and modalities to be used and the amount, frequency and duration. The therapist, other agency personnel and external home care providers (where applicable) shall participate in developing the plan of care.
- (C) The total plan of care shall be reviewed by the attending physician or attending intermediate care provider and HCA personnel as often as the severity of the consumer's condition requires, but at least once every 60 days or more frequently when there is a significant change in condition.
- (D) Agency professional staff shall promptly alert the physician or attending intermediate care provider to any changes that suggest a need to alter the plan of care.
- (E) If person-to-person contact was not completed or if awaiting a return response, all contacts and interactions shall be documented. The agency shall have a written policy regarding how the agency will intervene if the attending care provider cannot be contacted or does not respond timely.
 - (1) All orders shall contain sufficient information to carry out the order, name of the physician, intermediate care provider and, if appropriate, representative conferring the order to the HCA.

7.11 Medication management

- (A) If the plan of care includes medication administration, medication management or medication set-up, there shall be documentation as to who is responsible to monitor the medication supply, order refills and ensure the timely delivery of medications. There shall be evidence that the plan has been developed with input from the consumer or authorized representative.
 - (1) Medication review shall be documented when new medications are prescribed.
 - (2) Medical review shall be documented periodically throughout the episode of care to determine if the consumer has added or eliminated medications or herbal products from the medication regime.
- (B) Drugs and treatments shall be administered by agency staff only as ordered by the physician or intermediate care provider and in accordance with professional standards of practice.
 - (1) Influenza and pneumococcal polysaccharide vaccines may be administered per agency policy developed in consultation with a physician and after an assessment for contraindications.
 - (2) For consumers receiving medication administration services, a current medication administration record shall be maintained.

- (3) The health professional administering medication shall monitor for effectiveness, interactions and adverse effects.
- (C) If controlled drugs are being administered by the agency, there shall be a policy regarding how the drugs will be administered and monitored.
 - (1) Agencies shall have a written policy stating how controlled drugs will be monitored if agency staff transports the drugs from the pharmacy to the consumer.

7.12 Coordination

- (A) Care coordination shall be demonstrated for each consumer at least every 30 days for cases where there is more than one agency sharing the provision of the same home health services. The minutes of these case conferences shall reflect discussion and input by all the disciplines providing care to the consumer.
- (B) The HCA shall be responsible for the coordination of consumer services both with internal staff and known external services providing care and services to the same consumer.
- (C) All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care and as delineated through outside home care services.
- (D) The clinical record, care coordination notes or minutes of case conferences establish that effective interchange, reporting and coordination of consumer care do occur.
- (E) A written summary report for each consumer shall be documented and sent to the attending primary care provider at least every 60 days.

7.13 Extended care

Extended care is defined as a total of six (6) or more hours of home health services provided in a 24-hour period by a licensed agency that provides skilled health services.

- (A) The agency shall have a contingency plan regarding how the case is managed if a scheduled employee is unable to staff the case.
- (B) A communication record shall also be maintained in the home if a consumer is receiving extended care from a licensed or registered nurse.
 - (1) The record shall contain:
 - (a) The current plan of treatment,
 - (b) Notes containing consumer status and continuing needs.
 - (c) Medication administration record; and
 - (d) Any other information deemed necessary by the licensed agency.
 - (2) If nurse aide service is the only service providing extended care, a home communication record is not required. Written instructions shall be maintained in the home and in the permanent record.

- (C) The agency shall have an orientation plan for the staff providing the care to the consumers. Since extended care cases may involve highly technical services, this plan shall reflect how the agency ensures that the individuals providing the extended care are qualified to provide these types of services.
- (D) Contracting for extended care services
 - (1) A licensed HCA may contract with another entity to provide extended care in the licensed agency's service area provided that administration, care and supervision down to the consumer care level are ultimately the responsibility of the primary agency.
 - (2) The contract shall be in conformance with section 6.18 of this chapter.
 - (3) The contracted staff shall have completed the agency orientation and competency appraisal for provisions of care and services for the extended care consumer. Staff credentialing, orientation and competency appraisal documentation shall be kept at the primary agency.
- (E) Prior to withdrawing skilled nursing or nurse aide services for an extended care consumer, the HCA shall:
 - (1) Show continuing and documented efforts to resolve conflicts unless the safety of staff is placed at immediate risk;
 - (2) Provide evidence that ongoing efforts were made to recruit staff or place with another agency; and
 - (3) Give the consumer or authorized representative 15-business days notice of the intent to discharge the consumer unless staff or consumer safety is at immediate risk. The HCA shall have evidence that such notice was delivered in person or by certified mail.

7.14 Skilled nursing services

- (A) The registered nurse shall be responsible for the following:
 - (1) The initial evaluation visit,
 - (2) Regularly reevaluating the consumer's nursing needs,
 - (3) Initiating the plan of care and necessary revisions,
 - (4) Furnishing those services requiring substantial and specialized nursing skill,
 - (5) Initiating appropriate preventive and rehabilitative nursing procedures,
 - (6) Preparing clinical notes, coordinating services, and informing the physician and other personnel of changes in the consumer's condition and needs,
 - (7) Counseling the consumer and family in meeting nursing and related needs, and
 - (8) Participating in in-service programs, supervising and teaching other nursing personnel.

- (B) The licensed practical nurse shall be responsible for the following:
 - (1) Furnishing services in accordance with agency policies,
 - (2) Preparing clinical notes,
 - (3) Assisting the physician, intermediate care provider and registered nurse in performing specialized procedures.
 - (4) Preparing equipment and materials for treatments, observing aseptic technique as required, and
 - (5) Assisting the consumer in learning appropriate self-care techniques.

7.15 Nurse aide services

- (A) The agency shall select nurse aides on the basis of such factors as the ability to read, write, carry out directions, effectively communicate to demonstrate competency in the provision of care and services safely and effectively and treat consumers with dignity and respect to person and property.
- (B) The agency shall ensure that each nurse aide it employs is certified by the Colorado Department of Regulatory Agencies within four (4) months of starting employment and that certification remains current. Each aide that provide care and services before certification shall be supervised in the home by direct observation at least weekly for the first month of employment and every two (2) weeks thereafter until certification is obtained.
- (C) The agency shall complete a competency assessment with direct observation of each nurse aide before assignment in accordance with section 7.16 of this chapter.
- (D) For all consumers who are receiving skilled care and need nurse aide services, the supervising healthcare professional shall, during supervisory visits, accomplish the following:
 - (1) Obtain the consumer's input, or that of the consumer's authorized representative, regarding the nurse aide assignment form including all tasks to be performed during each scheduled time period.
 - (a) Details such as, but not limited to, housekeeping duties and standby assistance shall be negotiated and included on the nurse aide assignment form so that all obligations and expectations are clear.
 - (b) The nurse aide assignment form shall contain information regarding special functional limitations and needs, safety considerations, special diets, special equipment and any other information that is pertinent to the care that will be given by the aide.
 - (c) The HCA shall ensure that the consumer or the consumer's authorized representative approves and signs the form, is provided a copy at the beginning of services and at least once per year thereafter.
 - (d) Provide each consumer and/or the consumer's authorized representative with a new copy of the consumer rights form and explain those rights at least annually.

- (e) If nurse aide services are provided to a consumer who is receiving in-home care by a health professional, the supervising health care professional, in accordance with the professional's scope of practice and state and federal law, shall make an on-site supervisory visit to the consumer's home no less frequently than every two (2) weeks to supervise the nurse aide. Direct observation of care being provided by the nurse aide shall occur at least every 60 days. More frequent direct supervision shall occur if there are adverse changes in the consumer's condition, complaints received associated with the provision of care by an aide, supervision requested by the nurse aide or consumer for specific issues or other matters concerning the provisions of care by the nurse aide.
- (f) If nurse aide services are provided to a consumer who is not receiving in-home care by a health professional, a supervisory visit with the nurse aide present at the consumer's home shall occur no less frequently than every 60 days. More frequent direct supervision shall occur if there are adverse changes in the consumer's condition, complaints received associated with the provision of care by an aide, supervision requested by the nurse aide or consumer for specific issues, or other matters concerning the provisions of care by the nurse aide.

7.16 Nurse aide training and orientation

- (A) The HCA shall ensure that skills learned or tested elsewhere can be transferred successfully to the care of the consumer in his/her place of residence. This review of skills could be done when the nurse installs an aide into a new consumer care situation, during a supervisory visit or as part of the annual performance review. A mannequin may not be used for this evaluation.
- (B) If the HCA's admission policies and the case-mix of HCA consumers demand that the aide care for individuals whose personal care and basic nursing or therapy needs require more complex training than the minimum required in the regulation, the HCA shall document how these additional skills are taught and validated.
- (C) The HCA shall establish a process for standardized, step-by-step observation and evaluation of nurse aide competency in the following subject areas prior to the assignment of tasks requiring direct observation of items (3), (9), (10) and (11) of this paragraph (C).
 - (1) Communications skills;
 - (2) Observation, reporting and documentation of consumer status and the care or service furnished;
 - (3) Reading and recording temperature, pulse and respiration;
 - (4) Basic infection control procedures;
 - (5) Basic elements of body functioning and changes in body function that shall 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 methods to work with, the populations served by the HCA including the need for respect of the consumer, his or her privacy and property;
 - (9) Appropriate and safe techniques in personal hygiene and grooming that include:
 - (a) Bathing
 - (i) Bed/sponge,
 - (ii) Tub, and
 - (iii) Shower,
 - (b) Shampoo
 - (i) Sink,
 - (ii) Tub, and
 - (iii) Bed,
 - (c) Nail and skin care,
 - (d) Oral hygiene, and
 - (e) Toileting and elimination;
 - (10) Safe transfer techniques and ambulation;
 - (11) Normal range of motion and positioning; and
 - (12) Adequate nutrition and fluid intake.
- (D) Written assignment and instructions for the nurse aide shall be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the nurse aide.
- (1) The nurse aide assigned and instructed to provide only those services the aide is permitted to perform under state law and deemed competent to perform.
 - (2) The written assignment reflects the consumer's plan of care orders.
 - (3) The written instructions of the assignment shall consider the skills of the nurse aide, the amount and kind of supervision needed and the specific nursing or therapy needs of the consumer.
 - (a) The written instructions shall detail the procedures for the consumer's unique care needs.
 - (b) The written instructions shall identify when the nurse aide should report to the supervising professional.
 - (4) The written assignment and instructions shall be reviewed every 60 days or more frequently as changes in the consumer's status and needs occur.

7.17 Therapy services

- (A) Any therapy service offered by the HCA directly or under arrangement shall be provided by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician or intermediate care provider in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical notes, advises and consults with the family and other agency personnel and participates in in-service programs.
- (B) Supervision of therapy assistants
 - (1) A physical therapist assistant, occupational therapy assistant or respiratory therapy assistant performs services directed from a written plan of care delegated and supervised by a qualified therapist, assists in preparing clinical notes and progress reports, participates in educating the consumer and family and participates in in-service programs. Onsite supervision shall occur in accordance with the agency's policies and procedures, plan of care and professional standards of practice.

7.18 Medical social services

- (A) If the agency furnishes medical social services, those services shall be given by a qualified social worker in accordance with the plan of care.
- (B) The social worker shall be responsible for the following:
 - (1) Assisting the physician, or intermediate care provider and other team members in understanding the significant social and emotional factors related to the health problems,
 - (2) Participating in the development of the plan of care,
 - (3) Preparing clinical notes,
 - (4) Working with the family,
 - (5) Using appropriate community resources,
 - (6) Participating in discharge planning and in-service programs, and
 - (7) Acting as a consultant to other agency personnel.

7.19 Other healthcare services

- (A) Any healthcare services offered by the HCA directly or under arrangement are given by a qualified healthcare professional or by qualified healthcare professional assistant under the supervision of a qualified healthcare professional and in accordance with the plan of care. The qualified healthcare professional assists the physician or intermediate care provider in evaluating the needs of the consumer, helps develop the plan of care (revising it as necessary), prepares clinical notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

(B) Supervision of assistants

- (1) An assistant to the healthcare professional performs services directed from a written plan of care, delegated, and supervised by a qualified health professional, assists in preparing clinical notes and progress reports, and participates in educating the consumer and family, and participates in in-service programs. Onsite supervision shall occur in accordance with policy and procedure, the plan of care and professional standards of practice.

Section 8. NON-MEDICAL/PERSONAL CARE

8.1 Governing body

- (A) Each agency shall have a governing body having legal authority and responsibility for the conduct of the agency. At least one (1) member shall have knowledge of agency operations.
- (B) For the purposes of this section, the governing body shall:
 - (1) Have bylaws or the equivalent, which shall be reviewed and revised as needed;
 - (2) The bylaws or the equivalent shall specify the objectives of the agency;
 - (3) Designate and employ an agency manager;
 - (4) Adopt, review annually and revise as needed, policies and procedures for the operation and administration of the agency;
 - (5) Review the operation of the agency at least annually;
 - (6) Keep minutes of all meetings;
 - (7) Provide and maintain a fixed office location, that provides for consumer confidentiality and a safe working environment; and
 - (8) Organize services furnished, administrative control and lines of authority for the delegation of responsibility down to the consumer care level that are clearly set forth in writing and are readily identifiable.

8.2 Administration

- (A) The agency shall have written administrative policies and procedures to ensure safe and adequate care of the consumer.

8.3 Agency manager

- (A) A licensed home care agency providing personal care services shall designate an agency manager to supervise the provision of those services.
- (B) The agency manager shall meet the following qualifications:
 - (1) Be at least 21 years of age, possess a high school diploma or GED, and at least one (1) year documented supervisory experience in the provision of personal care services;

- (2) Be able to communicate and understand return communication effectively in exchanges between the consumer, family representatives, and other providers;
 - (3) Have successfully completed an eight (8) hour agency manager training course. Additional related annual training that equals 12 hours shall be required in the first year and annually thereafter;
 - (a) Any person commencing service as an agency manager after January 1, 2011, shall meet the minimum training requirements approved by the department pursuant to section 8.3(D) of this chapter; or provide documented and confirmed previous job related experience or related education equivalent to successful completion of such program. The department may require additional training to ensure that all the required components of the training curriculum are met.
 - (b) A copy of the certificate of completion shall be retained in the agency manager's personnel file.
 - (c) Any person already serving as an agency manager on December 31, 2010, shall either meet subparagraph (3) above or meet the minimum training requirements in one of the following ways:
 - (i) Successful completion of a program approved by the department, pursuant to section 8.3(D) of this chapter, if completed within a period of six (6) months following January 1, 2011;
 - (ii) Submission of evidence of successful completion of such training within the previous five (5) years before January 1, 2011; or
 - (iii) Documented and confirmed previous job related experience equivalent to successful completion of such a program that encompasses the items in section 8.3(D)(2) of this chapter.
 - (4) Be familiar with all applicable local, state, and federal laws and regulations concerning the operation and provision of home care services.
- (C) The agency manager shall be responsible for ensuring:
- (1) The agency is in compliance with all applicable federal, state and local laws,
 - (2) Completion, maintenance and submission of such reports and records as required by the department,
 - (3) Ongoing liaison with the governing body, staff members and the community,
 - (4) A current organizational chart to show lines of authority down to the consumer level,
 - (5) Appropriate personnel, bookkeeping and administrative records and policies and procedures of the agency,
 - (6) Orientation of new staff, regularly scheduled in-service education programs and opportunities for continuing education for the staff,

- (7) Designation in writing the qualified staff member to act in the absence of the manager,
 - (8) Availability of the manager or designee for all hours that employees are providing services, and
 - (9) All marketing, advertising and promotional information accurately represent the HCA and address the care, treatment and services that the HCA can provide directly or through contractual arrangement.
- (D) An agency manager training program shall be approved by the department if:
- (1) The program or its components are conducted by an accredited college, university or vocational school; or an organization, association, corporation, group or agency with specific expertise in that area and the curriculum includes at least eight (8) actual hours of training.
 - (2) Instruction includes, at a minimum, discussion of each the following topics:
 - (a) Home care overview including other agency types providing services and how to interact and coordinate with each including limitations of personal care versus health care services,
 - (b) Regulatory responsibilities and compliance including, but not limited to,
 - (i) Consumer rights,
 - (ii) Governing body responsibilities,
 - (iii) Quality management plans,
 - (iv) Occurrence reporting, and
 - (v) Complaint investigation and resolution process.
 - (c) Personnel qualifications, experience, competency and evaluations, staff training and supervision,
 - (d) Needs of the fragile, ill and physically and cognitively disabled in the community setting regarding special training and staffing considerations, and
 - (e) Behavior management techniques.

8.4 Supervisor

- (A) The supervisor shall:
- (1) Be at least 18 years of age,
 - (2) Have appropriate experience or training in the home care industry or closely related personal care services in accordance with agency policy, and
 - (3) Have completed training in the provision of personal care services.

8.5 Personal care worker

- (A) A personal care worker shall have completed agency training or have verified experience in the provision of home care tasks to consumers and passed a competency evaluation.
- (B) Personal care service employees shall provide services in accordance with the policies and requirements of the agency as well as the service arrangements spelled out in the service plan.
- (C) The duties of personal care worker may include the following:
 - (1) Observation and maintenance of the home environment that ensures the safety and security of the consumer.
 - (2) Assistance with household chores including cooking and meal preparation, cleaning, and laundry.
 - (3) Assistance in completing activities such as shopping, and appointments outside the home.
 - (4) Companionship including, but not limited to, social interaction, conversation, emotional reassurance, encouragement of reading, writing and activities that stimulate the mind.
 - (5) Assistance with activities of daily living, personal care and any other assignments as included in the service plan.
 - (6) Completion of appropriate service notes regarding service provision each visit. Documentation shall contain services provided, date and time in and out, and a confirmation that care was provided. Such confirmation shall be according to agency policy.
- (D) In order to delineate the types of services that can be provided by a personal care worker, the following are examples of limitations where skilled home health care would be needed to meet higher needs of the consumer.
 - (1) Skin care. A personal care worker may perform general skin care assistance. A personal care worker may perform skin care only when skin is unbroken, and when any chronic skin problems are not active. The skin care provided by a personal care worker shall be preventative rather than therapeutic in nature and may include the application of non-medicated lotions and solutions, or of lotions and solutions not requiring a physician's prescription. Skilled skin care includes wound care other than basic first aid, dressing changes, application of prescription medications, skilled observation and reporting. Skilled skin care should be provided by an agency licensed to provide home health services.
 - (2) Ambulation. A personal care worker may generally assist consumers with ambulation who have the ability to balance and bear weight. If the consumer has been determined by a health professional to be independent with an assistive device, a personal services worker may be assigned to assist with ambulation.
 - (3) Bathing. A personal care worker may assist consumers with bathing. When a consumer has skilled skin care needs or skilled dressings that will need attention before, during or after bathing, the consumer should be in the care of an agency licensed to provide home health services.

- (4) Dressing. A personal care worker may assist a consumer with dressing. This may include assistance with ordinary clothing and application of support stockings of the type that can be purchased without a physician's prescription. A personal care worker shall not assist with application of an ace bandage and anti-embolic or pressure stockings that can be purchased only with a physician's prescription.
- (5) Exercise. A personal care worker may assist a consumer with exercise. However, this does not include assistance with a plan of exercise prescribed by a licensed health care professional. A worker may remind the consumer to perform ordered exercise program. Assistance with exercise that can be performed by a personal care worker is limited to the encouragement of normal bodily movement, as tolerated, on the part of the consumer and encouragement with a prescribed exercise program. A personal care worker shall not perform passive range of motion.
- (6) Feeding. Assistance with feeding may generally be performed by a personal service worker. Personal care workers can assist consumers with feeding when the consumer can independently chew and swallow without difficulty and be positioned upright. Unless otherwise allowed by statute, assistance by a personal care worker does not include syringe, tube feedings and intravenous nutrition. Whenever there is a high risk that the consumer may choke as a result of the feeding the consumer should be in the care of an agency licensed to provide home health services.
- (7) Hair care. As a part of the broader set of services provided to consumers who are receiving personal services, personal care workers may assist consumers with the maintenance and appearance of their hair. Hair care within these limitations may include shampooing with non-medicated shampoo or shampoo that does not require a physician's prescription, drying, combing and styling of hair.
- (8) Mouth care. A personal care worker may assist and perform mouth care. This may include denture care and basic oral hygiene. Mouth care for consumers who are unconscious, have difficulty swallowing or are at risk for choking and aspiration should be performed by an agency licensed to provide home health services.
- (9) Nail care. A personal care worker may assist generally with nail care. This assistance may include soaking of nails, pushing back cuticles without utensils, and filing of nails. Assistance by a personal care worker shall not include nail trimming. Consumers with a medical condition that might involve peripheral circulatory problems or loss of sensation should be under the care of an agency licensed to provide home health services to meet this need.
- (10) Positioning. A personal care worker may assist a consumer with positioning when the consumer is able to identify to the personal care staff, verbally, non-verbally or through others, when the positions needs to be changed and only when skilled skin care, as previously described, is not required in conjunction with the positions. Positioning may include simple alignment in a bed, wheelchair, or other furniture.
- (11) Shaving. A personal care worker may assist a consumer with shaving only with an electric or a safety razor.

- (12) Toileting. A personal care worker may assist a consumer to and from the bathroom, provide assistance with bedpans, urinals and commodes; pericare, or changing of clothing and pads of any kind used for the care of incontinence.
- (13) A personal care worker may empty urinary collection devices, such as catheter bags. In all cases, the insertion and removal of catheters and care of external catheters is considered skilled care and shall not be performed by a personal care worker.
- (14) A personal care worker may empty ostomy bags and provide assistance with other consumer-directed ostomy care only when there is no need for skilled skin care or for observation or reporting to a nurse. A personal care worker shall not perform digital stimulation, insert suppositories or give an enema.
- (15) Transfers. A personal care worker may assist with transfers only when the consumer has sufficient balance and strength to reliably stand and pivot and assist with the transfer to some extent. Adaptive and safety equipment may be used in transfers, provided that the consumer and personal care worker are fully trained in the use of the equipment and the consumer, consumer's family member or guardian can direct the transfer step by step. Adaptive equipment may include, but is not limited to wheel chairs, tub seats and grab bars. Gait belts may be used in a transfer as a safety device for the personal care worker as long as the worker has been properly trained in its use.
 - (a) A personal care worker shall not perform assistance with transfers when the consumer is unable to assist with the transfer. Personal care workers, with training and demonstrated competency, may assist a consumer in a transfer involving a lift device.
 - (b) A personal care worker may assist the informal caregiver with transferring the consumer provided the consumer is able to direct and assist with the transfer.
- (16) Medication Assistance. Unless otherwise allowed by statute, a personal care worker may assist a consumer with medication only when the medications have been pre-selected by the consumer, a family member, a nurse, or a pharmacist, and are stored in containers other than the prescription bottles, such as medication minders. Medication minder containers shall be clearly marked as to day and time of dosage and reminding includes: inquiries as to whether medications were taken; verbal prompting to take medications; handing the appropriately marked medication minder container to the consumer; and, opening the appropriately marked medication minder container for the consumer if the consumer is physically unable to open the container. These limitations apply to all prescription and all over-the-counter medications. Any irregularities noted in the pre-selected medications such as medications taken too often, not often enough or not at the correct time as marked in the medication minder container, shall be reported immediately by the personal care worker to the supervisor.

- (17) Respiratory care is considered skilled care and shall not be performed by a personal care worker. Respiratory care includes postural drainage, cupping, adjusting oxygen flow within established parameters, nasal, endotracheal and tracheal suctioning.
 - (a) Personal care workers may temporarily remove and replace a cannula or mask from the consumer's face for the purposes of shaving, washing a consumer's face.
 - (b) Personal care workers may set a consumer's oxygen flow according written instruction when changing tanks, provided the personal care worker has been specifically trained and demonstrated competency for this task.
- (18) Accompaniment. Accompanying the consumer to medical appointments, banking errands, basic household errands, clothes shopping, grocery shopping or other excursions to the extent necessary and as specified on the service plan may be performed by the personal care worker when all the care that is provided by the personal care staff in relation to the trip is unskilled personal care, as described in these regulations.
- (19) Protective oversight. A personal care worker may provide protective oversight including stand-by assistance with any personal care task described in these regulations. When the consumer requires protective oversight to prevent wandering, the personal care worker shall have been trained in appropriate intervention and redirection techniques.
- (20) Respite care and companionship. A personal care worker may provide respite and companionship in the consumer's home according to the service plan as long as the necessary provision of services during this time does not include skilled personal care services as described in this regulation.
- (21) Housekeeping services. A personal care worker may provide housekeeping services, such as dusting, vacuuming, mopping, cleaning bathroom and kitchen areas, meal preparation, dishwashing, linen changes, laundry and shopping in accordance with the service contract. Where meal preparation is provided, the personal care worker should receive instruction regarding any special diets required to be prepared.
- (E) In addition to the exclusions prescribed in the preceding section, the agency shall not allow personal care workers to:
 - (1) Perform skilled home health services as defined in section 3.20 of this chapter;
 - (2) Perform or provide medication set-up for a consumer; or
 - (3) Perform other actions specifically prohibited by agency policy, regulations or law.
- (F) Supervision of a personal care worker shall:
 - (1) Be performed by a qualified employee of the agency who is in a designated supervisory capacity and available to the worker for questions at all times;

- (2) Include evaluation of each personal care worker providing services at least annually. The evaluation shall include observation of tasks performed and relationship with the consumer; and
- (3) Provide on-site supervision at a minimum of every three (3) months and include an assessment of consumer satisfaction with services and the personal care worker's adherence to the service plan.
 - (a) For a service agency that provides only Supported Living Services or Children's Extensive Support Services through a program approved by the Colorado Department of Human Services, the criteria set forth in paragraph F(3) shall be accomplished by compliance with 2 CCR 503-1, Section 16, Developmental Disabilities Services.

8.6 Personal care worker training

- (A) All personal care staff shall complete agency orientation before independently providing services to consumers. Orientation shall include:
 - (1) Employee duties and responsibilities;
 - (2) A description of the services provided by the agency;
 - (3) The differences in personal care, nurse aide care and health care in the home including limiting factors for the provision of personal care;
 - (4) Consumer rights including freedom from abuse or neglect, and confidentiality of consumer records, personal, financial and health information;
 - (5) Hand washing and infection control;
 - (6) Assignment and supervision of services;
 - (7) Observation, reporting and documentation of consumer status and the service furnished;
 - (8) Emergency response policies and emergency contact numbers for the agency and for the individual consumer assigned, and
 - (9) Training and competency evaluation of appropriate and safe techniques in all personal care tasks for each assigned task to be conducted before completion of initial training.
- (B) Training within the first 45 days of employment shall be provided, in addition to orientation, which can include self-study courses with demonstration of learned concepts, and are applicable to the employee's responsibilities. Initial training shall include, but is not limited to:
 - (1) Communication skills with consumers such as those who have a hearing deficit, dementia, or other special needs;
 - (2) Appropriate training in accordance with the needs of special needs populations served by the agency including communication and behavior management techniques;

- (3) Appropriate and safe techniques in personal care tasks prior to assignment. Areas include bathing, skin care, hair care, nail care, mouth care, shaving, dressing, feeding, assistance with ambulation, exercises and transfers, positioning, bladder care, bowel care, medication reminding, homemaking tasks, and protective oversight;
 - (4) Recognizing emergencies and knowledge of emergency procedures including basic first aid, home and fire safety;
 - (5) The role of, and coordination with, other community service providers; and
 - (6) Maintenance of a clean, safe and healthy environment, including appropriate cleaning techniques and sanitary meal preparation.
- (C) Initial orientation or training shall not be required under the following circumstances:
- (1) A returning employee meets all of the following conditions:
 - (a) The employee completed the agency's required training and competency assessment at the time of initial employment,
 - (b) The employee successfully completed the agency's required competency assessment at the time of rehire or reactivation,
 - (c) The employee did not have performance issues directly related to consumer care and services in the prior active period of employment, and
 - (d) All orientation, training and personnel action documentation is retained in the personnel files.
 - (2) An employee with proof of current healthcare related licensure or certification is exempt from initial training in the provision of personal care tasks if such training is recognized as included in the training for that health discipline. The agency shall provide orientation and perform a competency evaluation to ensure the employee is able to appropriately perform all personal care tasks.
 - (3) An employee moving from one office to another in the same agency if previous training is documented and the offices have the same orientation and training procedures.
- (D) The agency is responsible for ensuring that the individuals who furnish personal care services on its behalf are competent to carry out all assigned tasks in the consumer's place of residence.
- (1) Prior to assignment, the agency manager or supervisor shall conduct a proof of competency evaluation involving the tasks listed in this subsection (D)(1), along with any other tasks that require specific hands-on application.
 - (a) Bathing,
 - (b) Skin care,
 - (c) Hair care,

- (d) Nail care,
 - (e) Mouth care,
 - (f) Shaving,
 - (g) Dressing,
 - (h) Feeding,
 - (i) Assistance with ambulation,
 - (j) Exercise and transfers,
 - (k) Positioning,
 - (l) Bladder and bowel care, and
 - (m) Medication reminding.
- (2) Performance of the ability to assist in the use of specific adaptive equipment if the worker will be assisting consumers who use the device.
- (E) The agency shall ensure that ongoing supervisory and direct care staff training occurs and shall consist of at least six (6) topics applicable to the agency's services every 12 months after the starting date of employment or calendar year as designated by agency policy. The training requirement shall be prorated in accordance with the number of months the employee was actively working for the agency. Training shall include, but is not limited to, the following items:
 - (1) Behavior management techniques and the promotion of consumer dignity, independence, self-determination, privacy, choice and rights; including abuse and neglect prevention and reporting requirements.
 - (2) Disaster and emergency procedures.
 - (3) Infection control using universal precautions.
 - (4) Basic first aid and home safety.
- (F) Training documentation
 - (1) All training shall be documented.
 - (a) Classroom type training shall be documented with the date of the training; starting and ending times; instructors and their qualifications; short description of content; and staff member's signature.
 - (b) On-line or self-study training shall be documented with information as to the content of the training and the entity that offered or produced the training.

Editor's Notes

6 CCR 1011-1 has been divided into separate chapters for ease of use. Versions prior to 05/01/2009 are located in the main section, 6 CCR 1011-1. Prior versions can be accessed from the All Versions list on the rule's current version page. To view versions effective on or after 05/01/2009, select the desired chapter, for example 6 CCR 1011-1 Chap 04 or 6 CCR 1011-1 Chap 18.

History

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Chapter 26 Section 5.4.8 eff. 09/30/2011.

Chapter 26 Section 5.4 eff. 03/01/2012.

Chapter 26 Sections 5.4.4 – 5.4.7 eff. 03/02/2014.