

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 Chapter 26

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

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PART 1. STATUTORY AUTHORITY AND APPLICABILITY

1.1 Statutory Authority

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 Applicability

- (A) A home care agency, as defined herein, shall comply with all applicable federal, state, and local laws and regulations, including but not limited to, the following:
 - (1) This Chapter 26 as it applies to the type of services provided.
 - (2) 6 CCR 1011-1, Chapter 2, General Licensure Standards, unless otherwise modified herein.
- (B) Contracted services performed on behalf of the home care agency shall meet the standards established herein.

PART 2. DEFINITIONS

- 2.1 “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 their interests regarding care, treatment, and services provided by the home care agency. The authorized representative shall not be the home care consumer’s service provider except as allowed by state Medicaid programs.

- 2.2 “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 close to share administration, supervision, personnel, and services in a manner that renders it unnecessary for the branch to independently meet the requirements of this chapter.
- 2.3 “Bylaws” means a set of rules adopted by a home care agency for governing the agency’s operation. For purposes of this Chapter 26, “governing documents” is synonymous with “bylaws”.
- 2.4 “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.
- 2.5 “Clinical note” means a written notation of a healthcare contact with a consumer that is signed, with date and time, by personnel 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.
- 2.6 “Community Centered Board” means a community-centered board, as defined in Section 25.5-10-202, C.R.S., that is designated pursuant to Section 25.5-10-209, C.R.S., by the Department of Health Care Policy and Financing.
- 2.7 “Department” means the Colorado Department of Public Health and Environment.
- 2.8 “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.
- 2.9 “Governing body” means the board of trustees, directors, or other governing entity in whom the ultimate authority and responsibility for the conduct of the home care agency is vested.
- 2.10 “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 of 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 that 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 18 or 19 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 part;
 - (9) Services provided by a qualified early intervention service provider and overseen jointly by the Department of Education and the Department of Human Services; or
 - (10) A program of all-inclusive care for the elderly (PACE), established in Section 25.5-5-412, C.R.S., and regulated by the Department of Health Care Policy and Financing and the CMS, except that PACE home care services are subject to regulation in accordance with Section 25-27.5-104(4).
- 2.11 "Home care consumer" means a person who receives skilled home health services or personal care services in their temporary or permanent home or place of residence from a home care agency or from a provider referred by a home care placement agency. A home care consumer is also referred to in this chapter as "consumer".
- 2.12 "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, directly or by contract, to a home care consumer in the home care consumer's temporary or permanent home or place of residence. Such organizations shall follow the requirements of Section 25-27.5-101, et seq., C.R.S., that pertain to home care placement agencies and Part 3 of this chapter.
- 2.13 "Informal caregiver" means a person who provides care to the consumer without payment and who is not an employee of the agency.
- 2.14 "Licensed independent practitioner" means an individual permitted by law and the HCA to independently diagnose, initiate, alter, or terminate health care treatment within the scope of their license, and includes Advanced Practice Registered Nurses (APRN) and Physician Assistants.
- 2.15 "Manager" or "administrator" means any person who is responsible for and supervises or offers or attempts to oversee and supervise the day-to-day operations of a home care agency or home care placement agency.
- 2.16 "Nurse aide" means a nurse aide certified by the Colorado Department of Regulatory Agencies (DORA) or a nurse aide who has completed the requisite training and is within four (4) months of achieving certification.
- 2.17 "Owner" means a shareholder in a for-profit or nonprofit corporation, a partner in a partnership or limited partnership, a member in a limited liability company, a sole proprietor, or a person with a similar interest in an entity, who has at least a fifty-percent (50%) ownership interest in the business entity.

- 2.18 "PACE home care services" means skilled home health services or personal care services:
- (A) Offered as part of a comprehensive set of medical and nonmedical benefits, including primary care, day services, and interdisciplinary team care planning and management by PACE providers to an enrolled participant in the program of all-inclusive care for the elderly established in Section 25.5-5-412, C.R.S. and regulated by the Department of Health Care Policy and Financing and the CMS; and
 - (B) Provided in the enrolled participant's temporary or permanent place of residence.
- 2.19 "Parent agency" means the agency that develops and maintains administrative control of branch offices.
- 2.20 "Personal care services" means assistance with activities of daily living, including but not limited to: bathing, dressing, eating, transferring, walking or mobility, toileting, continence care, 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 themselves were they 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.
- 2.21 "Personnel" means individuals employed by and/or providing services under the direction of the HCA, including but not limited to: managers, administrators, staff, employees, contractors, students, interns, or volunteers.
- 2.22 "Plan of care" means a plan developed in consultation with the licensed independent practitioner and agency staff that covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, instructions for timely discharge or referral, and any other appropriate items.
- 2.23 "Plan of correction" means a written plan prepared by the home care agency or home care placement agency and submitted to the Department for approval that specifies the measures the agency shall take to correct all cited deficiencies.
- 2.24 "Pseudo-patient" means a person trained to participate in a role-play situation or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the nurse aide and must demonstrate the general characteristics of the primary consumer population served by the HCA in key areas such as age, frailty, functional status, and cognitive status.
- 2.25 "Qualified Early Intervention Service Provider" has the same meaning set forth in Section 27-10.5-702, C.R.S.
- 2.26 "Respite care" means services provided to a consumer who is unable to care for themselves on a short term basis because of the absence or need for relief of those persons normally providing care.

- 2.27 “Service Agency” means a service agency, as defined in Section 25.5-10-202, C.R.S., that has received certification from the Department of Health Care Policy and Financing as a developmental disabilities service agency under rules promulgated by the medical service board and is providing services pursuant to the supported living services waiver or the children’s extensive service support waiver or the home and community-based services waivers administered by the Department of Health Care Policy and Financing under Part 4 of Article 6 of Title 25.5, C.R.S.
- 2.28 “Service note” means a written notation that is signed, with date and time, by personnel of the home care agency furnishing the non-medical services.
- 2.29 “Skilled home health services” means health and medical services furnished in the consumer’s temporary or permanent home or 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; certified nurse aide services that require the supervision of a licensed or certified health care professional acting within the scope of their 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.
- 2.30 “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.
- 2.31 “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 healthcare agency.
- 2.32 “Supervision” means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity.
- 2.33 “Workstation” means a location separate from the parent agency that operates solely for the convenience of direct care staff. Any non-medical, medical, state, or federally certified agency may establish a workstation within the agency’s geographic service area. The site may provide a place to work so that direct care staff can decrease travel. Consumer charts are not to be kept at a workstation, but the site may contain phones, faxes, office supplies, wound care supplies, policies, procedures, forms, etc. The workstation shall not be used to accept referrals; conduct marketing, administrative activities, or personnel training; or store consumer records. The workstation shall not be staffed to serve the public and signage at the workstation shall not be posted to invite the public inside to conduct business.

PART 3. PLACEMENT AGENCIES

3.1 Registration

- (A) It is unlawful for a person to conduct or maintain a home care placement agency without a valid, current home care placement agency registration issued by the Department.
- (B) A person who violates any part of this section is:
- (1) Guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than \$50, nor more than \$500; and

- (2) May be subject to a civil penalty assessed by the Department of up to \$10,000 for each violation. The penalty shall be assessed, enforced, and collected in accordance with Article 4 of Title 24, C.R.S., and any penalties collected by the Department shall be transferred to the state treasurer for deposit in the general fund.

3.2 Criminal History Record Check

- (A) The home care placement agency shall require any provider seeking placement to submit to a criminal history record check to ascertain whether the provider applying has been convicted of a felony or misdemeanor, which felony or misdemeanor involves conduct that the agency determines could pose a risk to the health, safety, or welfare of home care consumers.
- (B) The criminal history record check shall, at a minimum, include a search of criminal history in the State of Colorado and be conducted not more than ninety (90) days prior to placement of the provider.
- (C) The cost of such inquiry shall be paid by either the home care placement agency or the individual seeking placement.
- (D) In assessing whether to refer a provider with a felony or misdemeanor conviction, the home care placement agency shall consider the following factors:
 - (1) The history of convictions or pleas of guilty or no contest;
 - (2) The nature and seriousness of the crimes;
 - (3) The time that has elapsed since the conviction(s);
 - (4) Whether there are any mitigating circumstances; and
 - (5) The nature of the position for which the provider would be referred.
- (E) The home care placement agency shall develop and implement policies and procedures regarding the referral of any provider who is convicted of a felony or misdemeanor to ensure that the provider being referred does not pose a risk to the health, safety, and welfare of the home care consumer.

3.3 Disclosures

- (A) The home care placement agency shall provide a written disclosure notice to the home care consumer concerning the duties and employment status of the individual(s) providing services.
- (B) The disclosure notice, in the form and manner prescribed by the Department, shall be signed by the consumer or authorized representative before the start of services and shall include, at a minimum, the following information:
 - (1) That the home care placement agency is not the employer of any provider it refers to a home care consumer; and
 - (2) That the home care placement agency does not direct, control, schedule, or train any provider it refers.

- (C) The home care placement agency shall maintain proof that disclosures have been provided before referring a provider to a home care consumer.

3.4 Inspections

- (A) The Department may inspect, as it deems necessary, a home care placement agency's records on weekdays between 9 a.m. and 5 p.m. to ensure that the home care placement agency is in compliance with the criminal history record check, general liability insurance, and disclosure requirements.
 - (1) The home care placement agency shall retain its records for a period of seven (7) years and those records shall be readily available to the Department during inspections.
- (B) The Department shall make inspections as it deems necessary to ensure that the health, safety, and welfare of a home care placement agency's home care consumers are being protected. Inspections of a home care consumer's home are subject to the consent of the consumer to access the property.

3.5 Plan of Correction

For purposes of this chapter, a plan of correction against a registered home care placement agency shall be completed in accordance with 6 CCR 1011-1, Chapter 2, Part 2.10.4(B).

3.6 Intermediate Restrictions or Conditions

- (A) The Department may impose intermediate restrictions or conditions on a home care placement agency 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 personnel, owners, or operators of the home care placement 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, safety, or welfare, the Department shall provide the home care placement agency with written notice of the restriction or condition. No later than ten (10) calendar days after receipt of the notice, the home care placement 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 home care placement agency in writing, by telephone, or in person during an on-site visit.
 - (1) The home care placement 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 home care placement agency within two (2) business days.
- (D) After submission of an approved written plan, the home care placement 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 home care placement 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 a home care placement 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 home care placement agency pursuant to Section 24-4-105, C.R.S.

3.7 Enforcement and Disciplinary Sanctions

- (A) For purposes of this chapter, enforcement activities against a registered home care placement agency shall comply with 6 CCR 1011-1, Chapter 2, Part 2.11.
- (B) If the Department suspends, revokes, or refuses to renew a home care placement agency registration, the home care placement agency shall be removed from the registry maintained by the Department pursuant to Section 25-27.5-103(2)(a)(I), C.R.S.

3.8 Registration Procedure

- (A) An applicant for an initial or renewal home care placement agency registration shall provide the Department with a complete application including all information and attachments specified in the application form and any additional information requested by the Department. Each application shall include, at a minimum, the following:
 - (1) A non-refundable annual registration fee of \$870. Registrations will be valid for one year from the date of issue.
 - (2) Evidence of general liability insurance coverage that covers the home care placement agency and the providers it refers to home care consumers. Such coverage shall be maintained for the duration of the license period. The minimum amount of coverage is \$100,000 per occurrence and \$300,000 aggregate.
 - (3) The legal name of the entity and all other names used by it to provide home care placement services. The applicant has a continuing duty to notify the Department of all name changes at least thirty (30) calendar days prior to the effective date of the change.
 - (4) Contact information for the entity including mailing address, telephone and facsimile numbers, e-mail address, and website address, as applicable.
 - (5) The identity of all persons and business entities with a controlling interest in the home care placement agency, including administrators, directors, and managers. A sole proprietor shall provide proof of lawful presence in the United States in compliance with Section 24-76.5-103(4), C.R.S.

- (B) With the submission of an application for registration or within ten (10) calendar days after a change in the owner, manager, or administrator, each owner, manager or administrator of a home care placement agency shall submit a complete set of their fingerprints to the Colorado Bureau of Investigation for the purpose of conducting a state and national fingerprint-based criminal history record check.
 - (1) Each owner, manager, or administrator is responsible for paying the fee established by the Colorado Bureau of Investigation for conducting the criminal history record check.
 - (2) If the owner, manager, or administrator of the home care placement agency has been convicted of a felony or of a misdemeanor which felony or misdemeanor involves conduct that the Department determines could pose a risk to the health, safety, or welfare of the home care placement agency's consumers, the Department will not approve the application for registration.

PART 4. DEPARTMENT OVERSIGHT

4.1 License Classification

- (A) An HCA shall be issued a license consistent with the type and extent of services provided. Unless otherwise specified, each licensed HCA shall meet the requirements in Part 5 of this chapter as well as Parts 6 and/or 7 depending upon the services provided.
 - (1) Class A – a home care agency that provides any skilled healthcare service. Agencies with a Class A license may also provide personal care services.
 - (2) 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 HCA providing home care services that are regulated by the Colorado Department of Health Care Policy and Financing (HCPF), excluding certified agencies defined in Part 2.4 of this chapter, shall be licensed as a Class B agency unless otherwise specified below.
 - (1) Any HCA providing services regulated by HCPF that also provides skilled care or services delivered by a licensed professional shall be licensed as a Class A HCA.
 - (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 HCA participating in the In-Home Support Service program may be licensed as a Class A or B HCA and shall comply with both HCPF's regulations concerning those programs and the applicable portions 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.

- (C) Residential facilities
 - (1) Any residential facility that delivers skilled home health or personal care services that the facility is not otherwise licensed or certified to 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 Parts 5 through 7 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 home or 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) Pursuant to Section 25.5-10-202(22), C.R.S., Independent Residential Support Services do not require licensure by the Department.
- (E) 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 25-27.5-102, C.R.S., from the entity's obligation to apply for, and operate under, a license in accordance with these regulations.

4.2 License Procedure

- (A) The HCA shall comply with the requirements of 6 CCR 1011-1, Chapter 2, 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) With the submission of an application for licensure or within ten (10) calendar days after a change in the owner, manager, or administrator, each owner and each manager or administrator of a home care agency shall submit a complete set of their fingerprints to the Colorado Bureau of Investigation for the purpose of conducting a state and national fingerprint-based criminal history record check. Each owner, manager, or administrator is responsible for paying the fee established by the Colorado Bureau of Investigation for conducting the criminal history record check.
 - (1) The Department may acquire a name-based criminal history record check for an applicant who has twice submitted to a finger-print based criminal history record check and whose fingerprints are unclassifiable.
 - (2) When the results of a finger-print based criminal history record check of an applicant reveal a record of arrest without a disposition, the Department shall require that person to submit to a name-based criminal history record check.
 - (3) 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 a misdemeanor, which felony or misdemeanor involves conduct that the Department determines could pose a risk to the health, safety, or welfare of HCA consumers.
 - (4) Each HCA owner, applicant, or licensee is under an affirmative obligation to inform the Department if they are 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 Parts 4.7 and 4.8 of this chapter.
- (E) 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 thirty (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.
- (F) An HCA shall notify the Department thirty (30) days prior to making any changes to the branch office physical address or organization.
- (G) An HCA seeking a waiver of these regulations, or any other Department regulations, shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 5.

4.3 Provisional Licenses

- (A) The HCA shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 2.4 regarding provisional licenses, with the following additions:
 - (1) If requested by HCPF, the Department may issue a provisional license for a period of ninety (90) days to an agency that has applied to be a certified home care agency.
 - (2) No provisional license shall be granted before completion of a criminal background check and finding in accordance with Part 4.2 of this chapter.

4.4 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 HCA's initial or renewal license application. The fee total shall include any applicable branch and workstation fees as set forth in this section.
- (C) Initial licensure
 - (1) Each HCA license applicant shall specify the type and extent of services to be provided and request the appropriate license category based upon the criteria set forth in Part 4.1 of this chapter. The initial license fee shall be:
 - (a) Class A - \$3,000
 - (b) Class B - \$2,200
 - (2) Any currently licensed Class B HCA that desires to change its license category to a Class A HCA shall submit an initial license application and initial license fee for a Class A license.
- (D) Provisional licensure
 - (1) Any HCA approved by the Department for a provisional license shall submit a fee equal to fifteen percent (15%) of the applicable initial license fee for each provisional license term.
 - (2) The appropriate fee shall be submitted before issuance of the provisional license.
 - (3) 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 for initial licensure and any additional appropriate fees specified in Part 4.4.
- (E) Renewal licensure
 - (1) Base Fee. There shall be a base fee that is determined by the license category as defined in Part 4.1 of this chapter. The renewal license base fee shall be:
 - (a) Class A - \$1,550

- (b) Class B - \$1,325
 - (2) Additional volume fee. Each HCA shall report its annual admissions for the previous year on its license renewal application. If the number of annual admissions is fifty (50) or more, the HCA shall add the following amount to its base fee:
 - (a) 50 to 99 admissions - \$100
 - (b) 100 or more admissions - \$200
 - (3) Medicare or Medicaid service discount. Each HCA that is currently certified to provide Medicaid or Medicare services shall deduct \$100 from its base fee.
 - (4) Deeming discount. A license applicant that is accredited by an accrediting organization recognized by CMS as having deeming authority may be eligible for a ten percent (10%) discount off the base renewal license fee. In order to be eligible for this discount, the license applicant shall submit copies of its most recent recertification survey(s), and any plan(s) of correction with the most recent letter of accreditation showing the license applicant has full accreditation status in addition to a completed renewal application.
- (F) Branch and workstation fees
- (1) 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.
 - (a) An HCA shall submit a \$200 fee for each branch office as defined in Part 2.2 of this chapter.
 - (i) For existing branches, the fee shall be submitted with the license application.
 - (ii) For new branches, the fee shall accompany the notice of the HCA's intent to open a branch office pursuant to Part 5.2 of this chapter.
 - (b) An HCA that operates one or more work stations solely for the convenience of direct care staff shall pay a fee of \$50 per workstation.
- (G) Revisit fee
- (1) An HCA'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 which the HCA has failed to demonstrate appropriate correction of the cited deficiencies at the first on-site revisit.
 - (2) The fee shall be one hundred percent (100%) of the HCA'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.

- (H) Change of ownership fee
 - (1) Any HCA meeting the criteria set forth in 6 CCR 1011-1, Chapter 2, Part 2.6 shall pay a change of ownership fee. The fee shall be determined according to the license classifications set forth in Part 4.1 of this chapter and submitted with the change of ownership notice. The fee shall be:
 - (a) Class A - \$3,000
 - (b) Class B - \$2,200
- (I) Change of name and change of address fees
 - (1) A licensed HCA shall conform with the notification requirements of 6 CCR 1011-1, Chapter 2, Part 2.9.6 regarding any change in the HCA name or business address.
 - (2) A fee of \$75 shall accompany each notice of a change in HCA name or business address.

4.5 Inspections

- (A) The HCA shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Parts 2.9.4, 2.10.1, and 2.10.2 regarding inspections, with the following additions:
 - (1) The Department shall make such inspections as it deems necessary to ensure that the health, safety, and welfare of home care consumers are 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.
 - (a) 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 (2) hours of request if the last visit occurred fourteen (14) or more days prior to the request. The time for production may be extended at the Department's discretion.
 - (b) 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 thirty (30) minutes of request. The time for production may be extended at the Department's discretion.
 - (2) Inspections shall not be conducted in a home care consumer's home without the consumer's consent.

4.6 Plan of Correction

The HCA shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 2.10.4(B) regarding a plan of correction.

4.7 Intermediate Restrictions or Conditions

- (A) The Department may impose intermediate restrictions or conditions on a license, which 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 personnel, 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.

4.8 Enforcement and Disciplinary Sanctions

The provisions of 6 CCR 1011-1, Chapter 2, Part 2.11 regarding enforcement and disciplinary sanctions shall apply to all HCAs and home care placement agencies.

4.9 Civil Fines

If the Department assesses a civil fine pursuant to Part 4.7 of this chapter, the money received by the Department shall be transmitted to the state treasurer who shall credit the same to the general fund.

PART 5. GENERAL REQUIREMENTS FOR ALL LICENSE CATEGORIES

5.1 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 an HCA within Colorado and shall be licensed according to the services rendered.

5.2 Branch Offices

- (A) An HCA shall notify the Department in advance of its plan to establish a branch office. Notification shall include, at a minimum:
 - (1) A description of the services to be provided;
 - (2) The geographic area to be served by the branch office that is within a portion of the total geographic area served by the parent agency; and
 - (3) A description of how the parent agency will supervise the branch office on a daily basis.
- (B) A branch office, as an extension of the parent agency, may not offer services that are different than those offered by the parent agency.
- (C) The location of the branch, in relation to the parent agency, shall be such that the parent agency is able to ensure adequate supervision at all times.
 - (1) The parent agency shall be physically located so that sharing of administration, supervision, personnel, and services with the branch can occur on a daily basis, and to ensure that the branch office has back-up coverage ready and available to serve all consumers when they are scheduled to receive services.
 - (2) In the event the branch office is unable to meet the consumer's needs, the parent agency shall ensure all consumers continue to receive services when scheduled, in accordance with the consumer's care plan.
- (D) The parent agency administrator, manager, or supervisor shall conduct an on-site visit of the branch office in accordance with agency policy.
- (E) 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, personnel that meet the qualifications of a supervisor shall be available during all operating hours.
- (F) The branch office shall have a copy of all agency policies available and readily accessible to staff.
- (G) The parent agency shall ensure that consumer records are readily accessible to all staff providing care and services.
- (H) The parent agency shall be aware of the staffing, census, and any issues/matters affecting the operation of the branch office at all times.

5.3 Consumer Rights

- (A) The provisions of 6 CCR 1011-1, Chapter 2, Part 7, shall apply, with the following additions:
 - (1) Assurance of rights
 - (a) A complete statement of consumer rights, including the right to file a complaint with the Department, shall be distributed to all personnel upon hire.
 - (b) At a minimum, the HCA's policies and procedures shall specify that:
 - (i) The consumer or authorized representative has the right to be informed of the consumer's rights through an effective means of communication.
 - (ii) 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.
 - (iii) The HCA shall protect and promote the exercise of these rights.
 - (2) Exercise of rights and respect for property and person
 - (a) The rights of the consumer may be exercised by the consumer or authorized representative without fear of retribution or retaliation.
 - (b) The consumer has the right to have their person and property treated with respect.
 - (c) The consumer has the right to be free from neglect; financial exploitation; and verbal, physical, and psychological abuse, including humiliation, intimidation, or punishment.
 - (d) 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.
 - (e) The consumer has the right to be served by agency staff who are properly trained and competent to perform their duties.
 - (f) 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 2, Part 8.
 - (g) The consumer or authorized representative has the right to express complaints verbally, or in writing, about services or care that are or are 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.
 - (h) The consumer has the right to confidentiality of all records, communications, and personal information.

- (i) The HCA shall advise the consumer of the agency's policies and procedures regarding disclosure of clinical information and records.
- (3) Right to be informed and to participate in planning care and services
 - (a) The HCA shall inform the consumer or authorized representative, in advance, about the care, method of delivery, and services to be furnished, and of any changes in the care, method of delivery, and services to be furnished, to enable the consumer to give informed consent.
 - (i) 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.
 - (ii) 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, the method of delivery of services and any changes in the method of delivery of services, and the consequences of refusing care or services.
 - (iii) The consumer has the right to refuse to change from an in-person method of delivery of services to a telehealth method of delivery. If the consumer refuses telehealth, their services shall continue in person.
 - (b) 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.
 - (i) 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.
- (4) The consumer has the right to receive prompt care in accordance with the care plan.
- (5) The consumer or authorized representative has the right to be advised of any changes in billing or payment procedures before implementation.
 - (a) If an HCA is implementing a scheduled rate increase to all consumers, the HCA shall provide a written notice to each affected consumer at least thirty (30) days before implementation.
 - (b) 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.
 - (c) 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.

- (6) The consumer or authorized representative has the right to be advised of the availability of the state's toll-free HCA hotline.
 - (a) 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.
- (7) 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.
 - (a) When a change of ownership occurs, the new owner shall send a written notice to all of the HCA's consumers listing all of the new owners and give the consumer the opportunity to continue services with the HCA or receive assistance in transferring care and services to a different HCA.
- (8) The HCA shall maintain documentation showing that it has complied with the requirements of this section.

5.4 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.

5.5 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 this finding in the consumer record.
- (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.
- (E) 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 forty-eight (48) hours of the occurrence.

5.6 Disclosure Notices

(A) Agency Disclosure Notice

- (1) Within one (1) business day of the start of services, the HCA shall provide a written disclosure notice to the consumer or authorized representative that specifies the service provided by the HCA and the consumer's obligation regarding the home care worker.
- (2) The disclosure notice, in the form and manner prescribed by the Department, shall be signed by the consumer or authorized representative and shall include information as to who is responsible for the following items:
 - (a) Employment of the home care worker;
 - (b) Liability for the home care worker while in the consumer's home;
 - (c) Payment of wages to the home care worker;
 - (d) Payment of employment and social security taxes;
 - (e) Payment of unemployment, worker's compensation, general liability insurance, and, if provided, bond insurance;
 - (f) Supervision of the home care worker;
 - (g) Scheduling of the home care worker;
 - (h) Assignment of duties to the home care worker;
 - (i) Hiring, firing, and discipline of the home care worker;
 - (j) Provision of materials or supplies for the home care worker's use in providing services to the consumer; and
 - (k) Training and ensuring qualifications that meet the needs of the consumer.
- (3) Within one (1) business day of the start of services, the HCA shall ensure that the consumer or authorized representative acknowledges the disclosure notice.
 - (a) In the event the consumer refuses to acknowledge the disclosure notice in writing, the HCA will document the conveyance of information verbally to the consumer or authorized representative.

- (B) Notice of Consumer 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 the form and manner prescribed by the Department and in a manner that the consumer understands.
 - (2) 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) 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.
- (D) Within one (1) business day of the start of services, the HCA shall inform the consumer or authorized representative, orally and in writing, 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.
- (E) When the HCA accepts the consumer for treatment or care, the HCA shall inform 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.
- (F) The HCA shall maintain documentation showing that it has complied with the requirements of this section.

5.7 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 are or are 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.
 - (a) 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 the HCA's quality assurance program in order to evaluate and implement systemic changes, where needed.
 - (4) An explicit statement that the HCA does not discriminate or retaliate against consumers for expressing a complaint or multiple complaints.
 - (5) Maintenance of a separate written or electronic record/log/file detailing all activity regarding complaints received and their investigation and resolution thereof.
 - (a) The record shall be maintained for at least a two (2) year period of time and shall be available for audit and inspection purposes.

5.8 Agency Reporting Requirements

- (A) The provisions of 6 CCR 1011-1, Chapter 2, Part 4.2, regarding occurrence reporting requirements shall apply to all HCAs and home care placement agencies.
- (B) The HCA shall develop and implement policies and procedures regarding the investigation of reportable occurrences and any alleged incidents involving neglect, abuse, or personnel misconduct, including but not limited to:
 - (1) The timely investigation of all alleged incidents involving neglect, abuse, or personnel misconduct.
 - (2) The investigation of each reportable occurrence and appropriate measures instituted to prevent similar future occurrences.
 - (a) A report with the investigation findings shall be available for review by the Department within five (5) working days of the occurrence.
 - (3) Administrative procedures to be implemented to protect the HCA's consumers during the investigation process.
 - (4) Documentation regarding the investigation, including the appropriate measures to be instituted, that shall be made available to the Department, upon request.
- (C) Nothing in this Part 5.8 shall be construed to limit or modify any statutory or common-law right, privilege, confidentiality, or immunity.
- (D) **Mandatory Reporting**
 - (1) HCA personnel engaged in the care or treatment of at-risk persons shall report suspected physical or sexual abuse, exploitation, and/or caretaker neglect to law enforcement within twenty-four (24) hours of observation or discovery pursuant to Section 18-6.5-108, C.R.S.
 - (2) HCA personnel engaged in the care or treatment of children shall report suspected abuse or neglect to the county department, local law enforcement, or to the child abuse reporting hotline pursuant to Section 19-3-304 and 307, C.R.S.
 - (3) The HCA shall ensure all personnel have knowledge of these requirements.
 - (4) The HCA shall report the incident to the Department as an occurrence, if applicable.

5.9 Personnel

- (A) **Policies**
 - (1) The HCA shall define the required competence, qualifications, and experience of personnel in each program or service it provides.
 - (2) The HCA shall ensure that all personnel have access to and are knowledgeable about the HCA's policies and procedures.

- (B) Records
 - (1) Personnel records shall include references, dates of employment and separation from the HCA, and the reason for separation.
 - (2) Personnel records shall include, at a minimum:
 - (a) Qualifications and licensure that are kept current;
 - (i) Qualifications include confirmation of type and depth of experience, advanced skills, training, and education; appropriate, detailed, and observed competency evaluation; and written testing overseen by a person with the same or higher validated qualifications;
 - (b) Orientation to the agency;
 - (c) Job descriptions for all positions assigned by the agency; and
 - (d) Annual performance evaluation for each employee.
- (C) Criminal History Record checks
 - (1) The HCA shall require any individual seeking employment with the agency to submit to a criminal history record check to ascertain whether the individual seeking employment has been convicted of a felony or misdemeanor, which felony or misdemeanor involves conduct that the agency determines could pose a risk to the health, safety, or welfare of home care consumers.
 - (2) The criminal history record check shall, at a minimum, include a search of criminal history in the State of Colorado and be conducted not more than ninety (90) days prior to employment of the individual.
 - (3) The cost of such inquiry shall be paid by either the HCA or the individual seeking employment.
 - (4) In assessing whether to employ an applicant with a felony or misdemeanor conviction, the HCA shall consider the following factors:
 - (a) The history of convictions or pleas of guilty or no contest;
 - (b) The nature and seriousness of the crimes;
 - (c) The time that has elapsed since the conviction(s);
 - (d) Whether there are any mitigating circumstances; and
 - (e) The nature of the position for which the applicant would be employed.
 - (5) 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.

- (D) Before employing any individual to provide direct consumer care or services, the HCA must show compliance with the Colorado Adult Protective Services Data System (CAPS Check) requirements as set forth in Section 26-3.1-111, C.R.S., and 6 CCR 1011-1, Chapter 2, Part 2.3.6.
- (E) Before employing any individual to provide direct consumer care or services, the agency shall contact the 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.
- (F) Contracted Personnel
 - (1) If contracted personnel are used by the HCA, the HCA shall have a written contract with such personnel that specifies the following:
 - (a) That consumers are accepted for care only by the primary HCA;
 - (b) The specific services to be furnished;
 - (c) The necessity to conform to all applicable agency policies, including personnel qualifications;
 - (d) The responsibility for participating in developing plans of care or service;
 - (e) The manner in which services will be controlled, coordinated, and evaluated by the primary HCA;
 - (f) The procedures for submitting clinical/service notes, scheduling of visits, and periodic consumer evaluation; and
 - (g) The procedures for payment for services furnished under the contract.
 - (2) Personnel policies shall be available to all contracted personnel.

5.10 Emergency Preparedness

- (A) The HCA shall conduct a risk assessment of the hazards or potential emergency situations the HCA could encounter.
 - (1) This assessment shall address, but not be limited to, the following considerations:
 - (a) Geographical location of the HCA, any branch offices and workstations, and its consumers;
 - (b) Needs of the HCA's consumer population; and
 - (c) Potential natural and human-made crises that impact the HCA's ability to operate, including but not limited to: extreme weather, fire, power or internet/communication outages, threatened or actual acts of violence, and pandemic or disease outbreak events.
 - (2) The assessment shall be documented.
 - (3) The assessment shall be reviewed at least annually and updated as necessary.

- (B) The HCA shall develop a written emergency preparedness plan, based on the results of the assessment required in Part 5.10(A), that is designed to manage consumers' care and services. The HCA shall implement the plan in response to the consequences of natural disasters or other emergencies that disrupt the HCA's ability to provide care and services or threaten the lives or safety of its consumers.
- (C) The emergency preparedness plan shall be reviewed at least annually or after any emergency response and shall be updated as necessary.
- (D) Personnel shall be trained on the emergency preparedness plan upon hire and at least annually or when any changes in the emergency preparedness process, procedures, or responsibilities are made.
- (E) At a minimum, the emergency preparedness plan shall include the following:
 - (1) Strategies for addressing emergency situations identified by the risk assessment;
 - (2) Identification of personnel responsible for responding to emergency situations and implementing the plan;
 - (3) Procedures to contact personnel and consumers impacted by an emergency;
 - (4) A mechanism for assessing and triaging the needs of its consumers to ensure continuation of necessary care for all consumers during an emergency. The HCA shall continually assess the status of its consumers to ensure they are triaged appropriately based on needs;
 - (5) Strategies for continuing to provide consumer services when there are interruptions in the supply of essentials, including but not limited to: water, pharmaceuticals, and personal protective equipment (PPE);
 - (6) Education for consumers, caregivers, and families on how to handle care and treatment, safety, and/or well-being during and following instances of natural and other disasters, including strategies and resources for ensuring access to life sustaining supplies, appropriate to the needs of the consumer;
 - (7) Strategies to protect and transfer consumer records, if necessary; and
 - (8) Strategies for continuing consumer care in the event the HCA is unable to access consumer records.

5.11 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.

5.12 Quality Management Program

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 2, Part 4.1.

5.13 Infection Prevention and Control

- (A) The HCA shall provide training for its personnel regarding the agency's written infection prevention and control policies and procedures at the time of hire and at least annually.
- (B) The HCA shall evaluate the adequacy of its infection prevention and control policies and procedures at least annually, make any necessary substantive changes, and document such changes in writing or electronically.
- (C) Personnel Health – Communicable Disease Prevention
 - (1) It shall be the responsibility of the HCA to establish written policies concerning pre-employment physical evaluations and personnel health. Those policies shall include, but not be limited to:
 - (a) Work restrictions to be placed on direct care personnel who are known to be affected with any illness in a communicable stage or to be a carrier of a communicable illness or disease.

5.14 Missed Visits

- (A) The HCA shall have a mechanism for informing the consumer about scheduled visits in accordance with HCA policy. Documentation shall be maintained and alterations in the schedule shall be provided to the consumer in advance of any changes to the schedule, where possible.
 - (1) The HCA's policy shall address processes for HCA planning for coverage of personnel illness, vacation, holidays, and unexpected voluntary or involuntary termination of employment.
 - (2) If the consumer does not respond to let personnel 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 missed 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 personnel in sufficient quantity are employed by the agency or have other effective back-up plans to ensure the needs of the consumer are met.
 - (5) The back-up plan for scheduled services that cannot be delivered shall not include calling for an ambulance or other emergency services unless emergency services would have been warranted even if the scheduled personnel had been in the home and had delivered services.

5.15 Information Management System

- (A) Each HCA shall implement a policy and procedure for an effective information management system that is 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; and
 - (2) Organization of the consumer record utilizing standardized formats for documenting all care, treatment, and services provided to consumers according to HCA policy. Standardization shall not include pre-filled documentation of future care and services.
- (B) In addition, for electronic consumer records, policies and procedures shall be developed 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), an emergency service plan, and a back-up system for retrieval of data from storage and information in the operating system.
- (C) Content of Consumer Records
 - (1) All HCAs shall have a complete and accurate record for each consumer assessed, cared for, treated, or served.
 - (2) 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.
 - (3) 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.
 - (4) The record shall indicate if the service or visit was provided in person or via telehealth.
 - (5) 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.
- (D) Consumer records must be retained for five (5) years after the discharge of the consumer, unless state law requires a longer period of time.
 - (1) The HCA's policies shall provide for retention of consumer records even if it discontinues operation.
 - (a) When an HCA permanently discontinues operation, it shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 2.14.4.
 - (b) When an HCA discontinues operation, it shall inform the state agency of where clinical records will be maintained.
 - (2) A change of ownership does not constitute discontinuing operation.
 - (3) When an HCA has a change of ownership, the existing owner shall provide the new owner with all consumer records.

PART 6. SKILLED CARE

6.1 Governing Body

- (A) An HCA shall have an organized governing body consisting of members who singularly or collectively have business and healthcare experience sufficient to oversee the services provided by the HCA.
- (B) The governing body shall assume responsibility for:
 - (1) Compliance with all federal, state, and local laws and regulations.
 - (2) Quality consumer care, including annual review and approval of the HCA's Quality Management Plan.
 - (3) Development of policies and procedures which describe and direct functions or services of the HCA and protect consumer rights.
 - (4) Development of bylaws or governing document that shall include, at a minimum:
 - (a) A description of functions and duties of the governing body, officers, and committees, including a process for review of agency operations at least annually;

- (b) A statement of the authority and responsibility delegated to the administrator; and
 - (c) A requirement to meet at least annually.
- (5) Development of a policy and procedure for determining the qualifications of the administrator. Appointment of a qualified administrator, responsible for the HCA's overall functions, shall be documented in writing.
- (6) Review of the written agency evaluation report and other communications from the administrator or group of professional personnel with evidence of written response.
- (7) Establishing and ensuring the maintenance of a system of financial management and accountability.
- (8) Organizing 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.
- (9) Documentation of governing body meetings and activities.

6.2 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 governing body shall review and update the overall plan and budget at least annually.
- (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 develop and implement 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.
 - (2) The policies and procedures shall include the following:
 - (a) A process to provide an appropriate back-up system, including emergency services twenty-four (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 preventive maintenance conducted at defined intervals per manufacturer's guidelines.
- (D) Availability After Business Hours
 - (1) The HCA shall have a registered nurse or other appropriate health professional available after business hours.
 - (2) The HCA 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.

6.3 Agency Evaluation

- (A) The HCA's governing body or its designee shall conduct a comprehensive evaluation of the HCA's total operation at least annually.
- (B) The evaluation shall assure the appropriateness and quality of the HCA'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.
 - (1) The HCA shall implement an on-going mechanism for consumer involvement to provide input and comment regarding services provided by the HCA in accordance with HCA policy. Consumer input and commentary shall be provided to the governing body at least annually to identify trends or issues requiring consideration.
- (D) In evaluating each aspect of its total program, the HCA shall consider four (4) 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 HCA as a result of its findings.
- (F) Appropriate professionals representing the scope of the HCA's program shall evaluate the HCA's consumer records at least quarterly.
 - (1) The evaluation shall include a review of sample active and closed consumer records to ensure that HCA policies are followed in providing services, both directly 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 HCA.

6.4 Administrator

- (A) The administrator shall assume authority for the operation of the HCA's skilled health services, including but not limited to:
 - (1) Organizing and directing the HCA's ongoing functions;
 - (2) Employing qualified personnel and ensuring appropriate ongoing education and supervision of all personnel;
 - (3) Ensuring the accuracy of public information materials and activities;
 - (4) Implementing a budgeting and accounting system; and
 - (5) Designating in writing a qualified alternate administrator to act in the administrator's absence.
- (B) The administrator shall:
 - (1) Be at least twenty-one (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 (2) years healthcare or health service administration experience with at least one (1) 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 HCA'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, personnel, and the community;

- (4) Maintenance of 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 HCA;
 - (6) Maintenance of appropriate personnel, 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 personnel, and regularly scheduled in-service education programs and opportunities for continuing education are provided for the personnel;
 - (9) Availability of the administrator or designee at all hours personnel are providing services, at minimum, any eight (8) hour period between 7 a.m. and 7 p.m. Monday through Friday;
 - (10) 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; and
 - (11) Maintenance of a coordinated HCA-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HCA's quality management program.
- (D) Curriculum for administrator training
- (1) A first-time administrator or alternate administrator shall complete a total of twenty-four (24) clock hours of training in the administration of an HCA before the end of the first twelve (12) months after designation to the position.
 - (2) A first-time administrator or alternate administrator shall complete eight (8) clock hours of educational training in the administration of an HCA within the first month of employment. The eight (8) clock hours shall include, at a minimum, the following topics:
 - (a) Home care overview;
 - (b) Information on the licensing standards for the HCA; and
 - (c) Information on state and local laws applicable to the HCA.
 - (3) A first-time administrator or alternate administrator shall complete an additional sixteen (16) clock hours of educational training before the end of the first twelve (12) months after designation to the position. Any of the sixteen (16) clock hours may be completed prior to designation if completed during the twelve (12) months immediately preceding the date of designation to the position. The additional sixteen (16) clock hours shall include the following subjects and may include other topics related to the duties of an administrator:
 - (a) Consumer rights, governing body and administrator responsibilities, quality management plans, occurrence reporting, and complaint investigation and resolution process;

- (b) Personnel qualifications, experience, competency, and evaluations;
 - (c) Financial management;
 - (d) Ethics in healthcare;
 - (e) Needs of the fragile, ill, and physically and cognitively disabled in the community setting with special training and staffing considerations;
 - (f) Behavior management techniques;
 - (g) Staffing methodologies and oversight of scheduling;
 - (h) Staff training and supervision; and
 - (i) Limitations of personal care versus health care services.
- (4) The twenty-four (24) clock 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 HCA.
 - (a) If an HCA 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 HCA shall maintain documentation of this approval for review by inspectors.
- (5) Documentation of administrator or alternate administrator training must be on file at the HCA 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.
- (6) After completion of the twenty-four (24) clock hours of educational training within the first twelve (12) months after designation as a first-time administrator or alternate administrator, each must then complete the continuing education requirements in each subsequent twelve (12)-month period after designation.
- (7) An administrator shall complete twelve (12) clock hours of continuing education within each twelve (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.
 - (a) Any of the topics listed under the initial training requirements;
 - (b) Development and implementation of agency policies;
 - (c) Healthcare management;
 - (d) Ethics;
 - (e) Quality improvement;

- (f) Risk assessment and management;
 - (g) Financial management;
 - (h) Skills for working with consumers, families, and other professional service providers, including considerations for special populations served by the HCA;
 - (i) Community resources; and
 - (j) Marketing.
- (8) For an administrator or alternate administrator who has not served as an administrator for 180 days or more immediately preceding the date of designation, at least eight (8) of the twelve (12) clock hours within the first twelve (12) months after designation shall include the topics listed for first time administrators. The remaining four (4) 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.

6.5 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.
- (1) 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 of healthcare experience in the field of supervision including one (1) year of experience in home care or a closely related service.
- (B) The nursing or healthcare supervisor, 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.
- (C) The nursing or healthcare supervisor shall ensure oversight of all consumer care services and personnel, including but not limited to:
- (1) Making consumer and personnel assignments;
 - (2) Coordinating consumer care;
 - (3) Coordinating referrals;
 - (4) Assuring that consumer needs are continually assessed; and
 - (5) Assuring the development, implementation, and updates of the individualized plan of care.

6.6 Personnel

- (A) All personnel shall possess the education and experience to provide services in the homes of consumers in accordance with HCA policy, state practice acts, and professional standards of practice as set forth in this chapter.
- (B) Licensed, certified, and/or registered personnel shall have an active license, certification, or registration, issued by DORA with no restriction that would affect the ability to perform required duties, and shall provide services within their scope of practice.
- (C) Personnel not licensed, certified, or registered by DORA shall, at a minimum, meet the following requirements:
 - (1) 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 personnel. Training requirements shall be consistent with the program, services, and equipment the HCA provides and appropriate to the needs of the populations served.
 - (1) Training shall consist of at least twelve (12) topics applicable to the HCA's care and services every twelve (12) months after the starting date of employment or calendar year as designated by HCA policy. The training requirement shall be prorated in accordance with the number of months the individual was actively working for the agency.
 - (2) Training shall include, but not be 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 prevention and control.
 - (3) All training shall be documented by the HCA.
 - (a) Documentation of training shall include: the date of training; length of training; entity or instructor(s) that offered or produced the training; a short description of the content; and staff member's written or electronic signature or proof of attendance.

6.7 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 forty-eight (48) hours of referral, or within forty-eight (48) hours of the consumer's return home, or on the 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 healthcare professional.
 - (3) The initial assessment visit and comprehensive assessment may be conducted during the same visit.
- (B) Comprehensive assessment of consumers
 - (1) The HCA shall conduct 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 or licensed independent practitioner, the primary professional healthcare worker shall complete the comprehensive assessment.
 - (6) When nursing services are provided, 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 or licensed independent practitioner and to the nursing or healthcare supervisor, and these reports shall be acted upon.
 - (7) For consumers receiving intermittent respite and waiver services that are not provided within a continuous sixty (60) day period, a comprehensive assessment shall be accomplished before reinitiating services rather than the minimum time frames set forth below.
 - (8) 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 sixty (60) days beginning with the start-of-care date; and

- (b) Within forty-eight (48) hours of the consumer's return to the home from a hospital admission of twenty-four (24) hours or more, for any reason other than diagnostic tests or, for non-certified agencies, as ordered by the physician or licensed independent practitioner.
- (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 3 CCR 716-1, Nursing Rules and Regulations. If the HCA prohibits nurse delegation, the HCA shall have a policy that specifies such prohibition.

6.8 Plan of Care

- (A) Consumer care follow a written plan of care established and periodically reviewed by a physician or licensed independent practitioner. For PACE participants, the interdisciplinary team shall establish, follow, and periodically review the plan of care.
- (B) The plan of care shall be developed in consultation with the HCA personnel 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.
 - (1) 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.
 - (2) The plan of care reflects the participation of the consumer to the extent possible. The HCA communicates the plan of care to the consumer or authorized representative in a comprehensible way.
- (C) If a physician or licensed independent practitioner refers a consumer under a plan of care that cannot be completed until after an evaluation visit, the attending physician or licensed independent practitioner shall be consulted to approve additions or modifications to the original plan.
- (D) Orders for therapy services shall include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist, other HCA personnel, and external home care providers, where applicable, shall participate in developing the plan of care.
- (E) The plan of care shall be reviewed in its entirety by the attending physician or licensed independent practitioner and HCA personnel as often as the severity of the consumer's condition requires, but at least once every sixty (60) days or more frequently when there is a significant change in condition.
 - (1) For consumers receiving intermittent respite and waiver services that are not provided within a continuous sixty (60) day period, the time frame for review begins upon the re-initiation of care.

- (F) Licensed HCA personnel shall promptly alert the physician or licensed independent practitioner to any changes that suggest a need to alter the plan of care.
- (G) If person-to-person contact with the physician or licensed independent practitioner or their designated representative was not completed or if awaiting a return response, all contacts and interactions shall be documented. The HCA shall have a written policy regarding how the HCA will intervene if the attending physician or licensed independent practitioner cannot be contacted or does not respond in a timely manner.
- (H) All orders shall contain sufficient information to carry out the order, name of the physician or licensed independent practitioner, and, if appropriate, representative conferring the order to the HCA.
- (I) Any program or service offered by the HCA, directly or under arrangement, shall be provided in accordance with the plan of care and HCA policy and procedure.

6.9 Medication Management

- (A) If the plan of care includes medication administration, medication management, or medication set-up, there shall be documentation in the consumer record 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) Medication 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 HCA personnel only as ordered by the physician or licensed independent practitioner and in accordance with professional standards of practice.
 - (1) Vaccines may be administered per HCA 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 as part of the consumer record.
 - (3) The personnel administering medication(s) shall monitor for effectiveness, interactions, and adverse effects.
- (C) If controlled drugs are being administered by the HCA, there shall be a policy regarding how the drugs will be administered and monitored.
 - (1) HCAs shall have a written policy stating how controlled drugs will be monitored if HCA personnel transport the drugs from the pharmacy to the consumer.

6.10 Care Coordination

- (A) Care coordination shall be demonstrated for each consumer at least every sixty (60) days for cases where there is more than one (1) 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 personnel and known external services providing care and services to the same consumer.
- (C) All personnel providing care on behalf of the HCA shall maintain communication 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) The HCA shall prepare a written summary report which shall be sent to the attending primary care provider every sixty (60) days. This report is only required for consumers who experienced a change in status or needs that necessitated a change in the plan of care during the sixty (60)-day period.

6.11 Extended Care

- (A) Extended care is defined as a total of six (6) or more hours of home health services provided in a twenty-four (24)-hour period by a licensed agency that provides skilled health services on a continuous basis.
- (B) The HCA shall have a contingency plan regarding how the care is managed if the scheduled personnel cannot provide care.
- (C) A communication record shall also be available in the home if a consumer is receiving extended care.
 - (1) The record shall contain:
 - (a) The current plan of care;
 - (b) Notes containing consumer status and continuing needs;
 - (c) The medication administration record; and
 - (d) Any other information deemed necessary by the HCA.
 - (2) If nurse aide service is the only service providing extended care, a home communication record is not required.
 - (a) Written instructions shall be maintained in the home and in the permanent record.
- (D) The HCA shall have an orientation plan for the personnel providing care to the consumers. Since extended care cases may involve highly technical services, this plan shall reflect how the HCA ensures that the individuals providing the extended care are qualified to provide these types of services.

- (E) Contracting for extended care services
 - (1) A licensed HCA may contract with another entity to provide extended care in the licensed HCA's service area provided that administration, care, and supervision down to the consumer care level are ultimately the responsibility of the primary HCA.
 - (2) The contract shall be in conformance with Part 5.9(F) of this chapter.
 - (3) The contracted personnel shall have completed the HCA orientation and competency evaluation for provisions of care and services for the extended care consumer.
 - (a) Documentation of personnel qualifications, orientation, and competency evaluation shall be kept at the primary HCA.
- (F) 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 personnel is placed at immediate risk;
 - (2) Provide evidence that ongoing efforts were made to recruit personnel or place the consumer with another HCA; and
 - (3) Give the consumer or authorized representative fifteen (15)-business days' notice of the intent to discharge the consumer unless staff or consumer safety is at immediate risk.
 - (a) The HCA shall maintain evidence that such notice was delivered in person or by certified mail.

6.12 Skilled Nursing Services

- (A) The registered nurse shall be responsible for the following:
 - (1) Conducting the initial assessment and comprehensive assessment 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) Performing nursing services in accordance with their scope of practice and as assigned by the physician, licensed independent practitioner, and/or registered nurse;
- (2) Furnishing services in accordance with HCA policies;
- (3) Preparing clinical notes; and
- (4) Assisting the consumer in learning appropriate self-care techniques.

6.13 Nurse Aide Services

- (A) The HCA 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 safe and effective provision of care and services, and treat consumers with dignity and respect to person and property.
- (B) The HCA shall ensure that each nurse aide it employs is certified by DORA within four (4) months of starting employment and that certification remains current. Each aide that provides care and services prior to 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.
 - (1) HCAs that employ nurse aides awaiting certification shall do so in accordance with Section 12-255-214, C.R.S.
- (C) The HCA shall complete a competency assessment with direct observation of each nurse aide before assignment, in accordance with Part 6.13(E) 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 nurse aide.
 - (c) The HCA shall ensure that the consumer or the consumer's authorized representative approves and signs the form and is provided a copy at the beginning of services, and at least annually.
 - (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 a supervisory visit no less than every two (2) weeks to supervise the nurse aide services. The visit shall be conducted either in the consumer's home or via telehealth, in accordance with the requirements in Part 6.17(A)(1).
 - (i) Direct observation of care being provided by the nurse aide shall occur at least every sixty (60) days in the consumer's home.
 - (ii) 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 a nurse 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 sixty (60) days.
 - (i) 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 a nurse aide, supervision requested by the nurse aide or consumer for specific issues, or other matters concerning the provisions of care by the nurse aide.
- (E) Nurse aide training and orientation
 - (1) The HCA shall ensure that skills learned or tested elsewhere can be transferred successfully to the care of the consumer in their place of residence. This review of skills may be performed 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 pseudo-patient may be used for this evaluation.
 - (2) If the HCA's admission policies and the case-mix of HCA consumers demand that the nurse 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.
 - (3) 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 (c), (i), (j), and (k) of this paragraph (3).
 - (a) Communications skills;
 - (b) Observation, reporting, and documentation of consumer status and the care or service furnished;
 - (c) Reading and recording temperature, pulse, and respiration;

- (d) Basic infection control procedures;
 - (e) Basic elements of body functioning and changes in body function that shall be reported to a nurse aide's supervisor;
 - (f) Maintenance of a clean, safe, and healthy environment;
 - (g) Recognizing emergencies and knowledge of emergency procedures;
 - (h) 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, their privacy, and property;
 - (i) Appropriate and safe techniques in personal hygiene and grooming that include: bathing, including bed/sponge, tub, and shower; shampoo, including sink, tub, and bed; nail and skin care; oral hygiene; and toileting and elimination;
 - (j) Safe transfer techniques and ambulation;
 - (k) Normal range of motion and positioning; and
 - (l) Adequate nutrition and fluid intake.
- (4) 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.
- (a) The nurse aide shall be assigned and instructed to provide only those services the aide is permitted to perform under state law and deemed competent to perform.
 - (b) The written assignment reflects the consumer's plan of care orders.
 - (c) 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.
 - (i) The written instructions shall detail the procedures for the consumer's unique care needs.
 - (ii) The written instructions shall identify when the nurse aide should report to the supervising professional.
 - (d) The written assignment and instructions shall be reviewed every sixty (60) days or more frequently as changes in the consumer's status and needs occur.

6.14 Therapy Services

- (A) Any therapy services 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.

- (B) The qualified therapist shall assist the physician or licensed independent practitioner in evaluating level of function, help develop the plan of care (revising it as necessary), prepare clinical notes, advise and consult with the family and other agency personnel, and participate in in-service programs.
- (C) 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.

6.15 Medical Social Services

- (A) Any medical social services offered by the HCA, directly or under arrangement, shall be provided 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 licensed independent practitioner 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) Connecting the consumer with appropriate community resources;
 - (6) Participating in discharge planning and in-service programs; and
 - (7) Acting as a consultant to other HCA personnel.

6.16 Other Healthcare Services

- (A) Any healthcare services offered by the HCA, directly or under arrangement, are given by a qualified healthcare professional or by a qualified healthcare professional assistant under the supervision of a qualified healthcare professional and in accordance with the plan of care.
- (B) The qualified healthcare professional assists the physician or licensed independent practitioner 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.
- (C) 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, participates in educating the consumer and family, and participates in in-service programs.

6.17 Telehealth Supervisory Visits

- (A) The HCA may conduct supervisory visits using telehealth for the following services, so long as the HCA continues to ensure consumer care and treatment are delivered in accordance with a plan of care that addresses the consumer's status and needs.
 - (1) For nurse aide services, the supervising healthcare professional may evaluate the delivery of care and services required every two (2) weeks at Part 6.13(D)(1)(e) through an interactive audiovisual connection with the consumer. The results of the supervisory visit must be documented by the supervising healthcare professional.
 - (a) An in-person supervisory visit with the nurse aide and consumer is required at least every sixty (60) days if nurse aide services are provided to a consumer who is receiving in-home care by a nurse aide.
 - (2) For therapy services, such as physical therapy, occupational therapy, and speech therapy, supervision of assistants required at Part 6.14(C) may be provided through an interactive audiovisual connection and in accordance with all applicable state laws and regulations.
 - (a) An in-person supervisory visit shall occur in accordance with the HCA's policies and procedures, the plan of care, and professional standards of practice.
 - (3) For other healthcare services, supervision of assistants required at Part 6.16(C) may be provided through an interactive audiovisual connection and in accordance with all applicable state laws and regulations.
 - (a) An in-person supervisory visit shall occur in accordance with the HCA's policies and procedures, the plan of care, and professional standards of practice.
- (B) An in-person supervisory visit is required to evaluate consumer complaints related to the delivery of care when such concerns cannot be successfully addressed remotely through an interactive audiovisual connection.
- (C) All other general requirements for supervisory visits, such as documentation and meeting the same standard of care, must be met.

6.18 Clinical Record

- (A) In addition to the requirements in Part 5.15, an HCA providing skilled care shall comply with the following requirements:
 - (1) The initial and comprehensive assessments shall be documented in the consumer record and shall include the consumer's current comprehensive assessment, including all of the assessments from the most recent HCA admission, clinical notes, plans of care, and physician or licensed independent practitioner orders.
 - (2) The record shall include all interventions, including medication administration, treatments, and services, and responses to those interventions.

PART 7. NON-MEDICAL/PERSONAL CARE

7.1 Governing Body

- (A) An HCA may choose to convene a governing body that shall have legal authority and responsibility for the conduct of the HCA. If an HCA does not convene a governing body, the HCA shall designate an individual who shall have responsibility for all tasks as set forth in this Part 7.1.
- (B) At least one (1) member of the governing body or designee shall have knowledge of HCA operations.
- (C) For the purposes of this section, the governing body or designee shall:
 - (1) Have bylaws or a governing document that shall specify the programs and services offered by the HCA and be reviewed and revised as needed;
 - (2) Designate and employ an HCA manager;
 - (3) Develop and adopt policies and procedures for the operation and administration of the HCA, to be reviewed annually and revised as needed;
 - (4) Ensure any program or service offered by the HCA, directly or under arrangement, shall be provided in accordance with the service plan and HCA policy and procedure;
 - (5) Review the operations of the HCA 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.
- (D) Agency Evaluation
 - (1) The HCA's governing body or designee shall conduct a comprehensive evaluation of the HCA's total operation at least annually.
 - (2) The evaluation shall assure the appropriateness and quality of the HCA's services with findings used to verify policy implementation, to identify problems, and to establish problem resolution and policy revision as necessary, and shall include any findings or improvement strategies identified by the HCA's Quality Management Program required in Part 5.12.
 - (3) The HCA shall implement a method for ongoing process improvement and policy and administrative review, which includes a review of the scope of services offered, arrangements for services with other agencies or individuals, admission and discharge policies, supervision and service plan, urgent consumer care, service records, and personnel qualifications.

- (a) The HCA shall implement an on-going mechanism for consumer involvement to provide input and comment regarding services provided by the HCA in accordance with HCA policy.
 - (b) All findings from the policy and administrative review and consumer input and commentary shall be provided to the governing body at least annually to identify trends or issues requiring consideration.
- (4) In evaluating each aspect of its total program, the HCA shall consider four (4) main criteria:
 - (a) Appropriateness - assurance that the area being evaluated addresses existing and/or potential problems.
 - (b) Adequacy - a determination as to whether the HCA has the capacity to overcome or minimize existing or potential problems.
 - (c) Effectiveness - the services offered accomplish the objectives of the HCA and anticipated consumer outcomes.
 - (d) Efficiency - whether there is a minimal expenditure of resources by the HCA to achieve desired goals and anticipated consumer outcomes.
- (5) 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 HCA as a result of its findings.
- (6) Appropriate qualified individuals representing the programs and services offered by the HCA shall evaluate the HCA's consumer records on an ongoing basis, but no less than quarterly.
 - (a) The evaluation shall include a review of sample active and closed consumer records to ensure that HCA policies are followed in providing services, both directly 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 HCA.

7.2 HCA Manager

- (A) The HCA's governing body or designee shall appoint an HCA manager to supervise the provision of the HCA's services.
- (B) The HCA manager shall meet the following qualifications:
 - (1) Be at least twenty-one (21) years of age, possess a high school diploma or GED, and have at least one (1) year documented supervisory experience in the provision of personal care services;
 - (a) If the HCA manager does not have the required one (1) year of experience supervising the delivery of personal care services, they shall demonstrate they have the following:

- (i) A college degree in healthcare services plus at least one (1) year of work experience in health care during the previous ten (10)-year period; or
 - (ii) A college degree in any field plus two (2) years of work experience in health care during the previous ten (10)-year period.
 - (2) Be able to communicate and understand return communication effectively in exchanges between the consumer, family representatives, and other providers, including the use of appropriate translator services as needed;
 - (3) Have successfully completed an eight (8) hour agency manager training course. Additional related annual training that equals twelve (12) hours shall be required in the first year and annually thereafter;
 - (a) Any person commencing service as an HCA manager shall meet the minimum training requirements approved by the Department pursuant to Part 7.2(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 HCA manager's personnel file.
 - (4) Be familiar with all applicable local, state, and federal laws and regulations concerning the operation and provision of home care services.
- (C) The HCA manager shall be responsible for ensuring:
 - (1) The HCA is in compliance with all applicable federal, state, and local laws;
 - (2) The completion, maintenance, and submission of reports and records as required by the Department;
 - (3) Ongoing liaison with the governing body or designee, staff members, and the community;
 - (4) Maintenance of a current organizational chart to show lines of authority down to the consumer level;
 - (5) Maintenance of appropriate personnel, bookkeeping, and administrative records and policies and procedures of the HCA;
 - (6) Orientation of new personnel, and regularly scheduled in-service education programs and opportunities for continuing education are provided for personnel;
 - (7) Designating 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 personnel are providing services;

- (9) 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;
 - (10) Maintenance of a coordinated HCA-wide program for appropriate infection prevention and control that is an integral part of the HCA's quality management program; and
 - (11) The implementation and monitoring of the HCA's training program for all homemakers and personal care workers, including managing or delegating employee training and development activities for the HCA.
- (D) An HCA 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 by 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 of the following topics:
 - (a) Home care overview including other agency types providing services and how to interact and coordinate, including limitations of personal care versus health care services;
 - (b) Regulatory responsibilities and compliance, including:
 - (i) Consumer rights,
 - (ii) Governing body or designee 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, cognitively, and/or developmentally disabled in the community setting regarding special training and staffing considerations; and
 - (e) Behavior management techniques.

7.3 Homemaker

- (A) A homemaker shall complete training, in accordance with the following requirements, prior to providing services independently.
- (B) A homemaker must complete training as specified in Part 7.3(C) and pass a competency evaluation that includes a visual observation and evaluation of relevant skills, prior to providing care to a consumer.

- (1) If the HCA utilizes another entity to provide the training, the HCA must validate that the training program meets the requirements in Part 7.3(C) below and retain evidence of the individual's successful completion of the training program in the personnel record.
- (C) Homemaker training
 - (1) All homemaker staff shall complete HCA training before independently providing services to consumers. Initial training must be interactive in nature and may be completed through the following modes: in-person, online/virtual, or a hybrid, with demonstration of learned concepts. Initial training shall include:
 - (a) Personnel duties and responsibilities, including but not limited to incident reporting and mandatory reporting;
 - (b) Rules for non-medical care and services as described in this chapter;
 - (c) The differences in homemaker and personal care;
 - (d) Consumer rights, including freedom from abuse or neglect and confidentiality of personal, financial, and health information;
 - (e) Basic health and safety, including but not limited to: home safety, fall prevention, hand washing, and infection control;
 - (f) Assignment and supervision of services;
 - (g) Communication skills;
 - (h) The physical, emotional, and developmental needs of and methods to work with the populations served and assignment of consumers by the HCA, including the need for respect of the consumer, their privacy, and property; and
 - (i) Training and core competency evaluation of homemaking and housekeeping skills shall be conducted before completion of initial training, including the evaluation of maintenance of a clean, safe, and healthy environment and the appropriate and safe techniques for each assigned task.
 - (2) The HCA shall provide orientation for all personnel upon hire that includes, but is not limited to HCA policies and procedures and emergency response policies and emergency contact numbers for the HCA and for the individual consumer(s) assigned.
 - (3) The HCA shall ensure that ongoing training of homemakers occurs and shall consist of at least four (4) training topics outlined in Part 7.3(C)(1) above every twelve (12) months after the starting date of employment or calendar year as designated by HCA policy. The training requirement shall be prorated in accordance with the number of months the employee was actively working for the HCA.
- (D) Homemakers shall provide services in accordance with the policies and requirements of the HCA as well as the service arrangements spelled out in the service plan.

- (E) The duties of a homemaker shall include the following:
 - (1) Reporting any observed environmental concerns or changes in the consumer's status that may impact the safety and security of the consumer to the HCA.
 - (2) Completion of appropriate service notes regarding service provision of each visit, to include confirmation of services provided and the date and time in and out. Such confirmation shall also be according to HCA policy.
- (F) The duties of a homemaker may include the following:
 - (1) Routine light house cleaning, meal preparation, dishwashing, and bed making. Homemakers may also assist in teaching these tasks to the consumer.
 - (a) Where meal preparation is provided in accordance with the service contract, the homemaker should receive instruction regarding any special diets required to be prepared.
 - (2) Assistance in completing activities outside the home, such as shopping or laundry.
 - (3) Companionship, including but not limited to: social interaction, conversation, emotional reassurance, encouragement of reading, writing, and activities that stimulate the mind.

7.4 Personal Care Worker

- (A) A personal care worker must meet all requirements in Part 7.3, Homemaker, in addition to the specific requirements for personal care workers outlined below, prior to providing services independently.
- (B) A personal care worker must complete training as specified in Part 7.4(C), personal care worker training, and pass a competency evaluation and skills validation, including visual observation, prior to providing care to a consumer.
- (C) Personal care worker training
 - (1) Initial training shall include the topics identified in homemaker training at Part 7.3(C)(1), in addition to the following:
 - (a) The differences in personal care, nurse aide care, and health care in the home including limiting factors for the provision of personal care as specified in Part 7.4(E) below;
 - (b) Observation, reporting, and documentation of consumer status and the service(s) furnished;
 - (c) Non-medical assistance with activities of daily living, including bathing, skin care, hair care, nail care, mouth care, shaving, dressing, feeding, assistance with ambulation, exercises and transfers, positioning, bladder care, bowel care, and protective oversight;
 - (d) Medication reminders; and

- (e) Performance of the ability to assist in the use of specific adaptive equipment if the worker will be assisting consumers who use the device.
- (2) The HCA shall provide orientation for all personnel upon hire that includes, but is not limited to, topics identified in homemaker orientation at 7.3(C)(2) and a description of the services provided by the HCA.
- (3) The HCA 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.
 - (a) Prior to assignment, the HCA manager or supervisor shall conduct a proof of competency evaluation involving the tasks listed in Part 7.4(C)(1)(c), (d), and (e), along with any other tasks that require specific hands-on application.
- (4) The HCA shall ensure that ongoing supervisory and direct care staff training occurs and shall consist of at least six (6) topics every twelve (12) months after the starting date of employment or calendar year as designated by HCA policy. The training requirement shall be prorated in accordance with the number of months the employee was actively working for the HCA. Training shall include, but is not limited to, the following items:
 - (a) Behavior management techniques and the promotion of consumer dignity, independence, self-determination, privacy, choice, and rights, including abuse and neglect prevention and reporting requirements.
 - (b) Disaster and emergency procedures.
 - (c) Infection control using universal precautions.
 - (d) Basic first aid and home safety.
- (D) The duties of a personal care worker shall include all duties outlined in homemaker duties at Part 7.3(E), in addition to the following:
 - (1) Observation and maintenance of the home environment in accordance with the service plan that ensures the safety and security of the consumer.
 - (2) Reporting any observed or stated changes in the consumer's physical, cognitive, and/or developmental status.
- (E) The duties of personal care worker may include all duties outlined in homemaker duties at Part 7.3(F), in addition to the following:
 - (1) Assistance with non-medical activities of daily living, personal care, and any other assignments as included in the service plan.
- (F) Personal care worker tasks. The purpose of this part is 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) A personal care worker may perform general skin care assistance.

- (b) A personal care worker may perform skin care only when skin is unbroken, and when any chronic skin problems are not active.
 - (c) 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.
 - (d) 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 HCA licensed to provide skilled home health services.
- (2) Ambulation
 - (a) A personal care worker may generally assist consumers with ambulation if they have the ability to balance and bear weight.
 - (b) If the health professional has determined that the consumer is independent with an assistive device, a personal services worker may be assigned to assist with ambulation.
- (3) Bathing
 - (a) A personal care worker may assist consumers with bathing only if they have the ability to balance and bear weight, except when a transfer involves a lift device as described in Part 7.4(F)(13)(d).
 - (b) 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 HCA licensed to provide skilled home health services for those needs.
- (4) Dressing
 - (a) A personal care worker may assist a consumer with dressing. This may include assistance with ordinary clothing and application of support stockings, including ace bandages and anti-embolic or pressure stockings that can be purchased without a physician's prescription.
 - (b) A personal care worker that assists a consumer with application of any support stocking must receive training from a qualified individual in the stocking's proper application. Prior to application and on an annual basis, the qualified individual shall conduct a proof of competency evaluation in the correct application of support stockings.
- (5) Exercise
 - (a) 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.

- (b) A personal care worker may remind the consumer to perform ordered exercise. 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.
 - (c) A personal care worker shall not perform passive range of motion.
- (6) Feeding
 - (a) Assistance with feeding may generally be performed by a personal service worker.
 - (b) Personal care workers can assist consumers with feeding when the consumer can independently chew and swallow without difficulty and be positioned upright.
 - (c) 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 HCA licensed to provide skilled home health services.
- (7) Hair care
 - (a) 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.
 - (b) Hair care may include shampooing, drying, combing, and styling of hair. Medicated shampoo or shampoo that requires a physician's prescription may not be used.
 - (c) Over-the-counter medicated shampoos may be used as part of the broader set of services provided to the consumer, if the personal care worker has been trained by the agency in the proper use of the product. Prior to application and on an annual basis, a qualified individual shall conduct a proof of competency evaluation in the correct use of these products.
- (8) Mouth care
 - (a) A personal care worker may assist and perform mouth care. This may include denture care and basic oral hygiene.
 - (b) Mouth care for consumers who are unconscious, have difficulty swallowing, or are at risk for choking and aspiration shall be performed by an HCA licensed to provide skilled home health services.
- (9) Nail care
 - (a) 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.

- (b) Assistance by a personal care worker shall not include nail trimming.
 - (c) Consumers with a medical condition that might involve peripheral circulatory problems or loss of sensation shall be under the care of an HCA licensed to provide skilled home health services.
- (10) Positioning
 - (a) 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.
 - (b) Positioning shall not exceed simple alignment in a bed, wheelchair, or other furniture.
 - (c) A personal care worker may assist a skilled home health worker with a consumer's positioning when any position change addresses skilled skin care concerns, as defined at Part 7.4(F)(1)(d). A personal care worker may not be assigned to or independently perform this function.
- (11) Shaving
 - (a) A personal care worker may assist a consumer with shaving only with an electric or a safety razor.
- (12) Toileting
 - (a) A personal care worker may assist a consumer to and from the bathroom; provide assistance with bedpans, urinals, and commodes; provide pericare; or change clothing and pads of any kind used for the care of incontinence.
 - (b) 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.
 - (c) 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.
- (13) Transfers
 - (a) 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.
 - (b) 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.

- (c) 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 and as long as the consumer is able to assist with the transfer.
 - (d) 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.
 - (e) 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.
- (14) Medication Assistance. The following requirements apply to all prescription and all over-the-counter medications:
 - (a) 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.
 - (b) 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.
 - (c) 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.
- (15) Respiratory Care
 - (a) 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.
 - (b) Personal care workers may temporarily remove and replace a cannula or mask from the consumer's face for the purposes of shaving and/or washing a consumer's face.
 - (c) Personal care workers may set a consumer's oxygen flow according to written instruction when changing tanks, provided the personal care worker has been specifically trained and demonstrated competency for this task.

- (16) Accompaniment
 - (a) 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.
- (17) Protective oversight
 - (a) A personal care worker may provide protective oversight including stand-by assistance with any personal care task described in these regulations.
 - (b) When the consumer requires protective oversight to prevent wandering, the personal care worker shall have been trained in appropriate intervention and redirection techniques.
- (18) Respite care
 - (a) A personal care worker may provide respite care 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 home health services as defined in Part 2.29 of this chapter.
- (G) In addition to the exclusions prescribed in the preceding section, the HCA shall not allow personal care workers to:
 - (1) Perform skilled home health services as defined in Part 2.29 of this chapter;
 - (2) Perform or provide medication set-up for a consumer; or
 - (3) Perform other actions specifically prohibited by HCA policy, regulations, or law.

7.5 Training Exemptions

- (A) Initial orientation or training shall not be required under the following circumstances:
 - (1) A returning employee is exempt from initial training if they are returning to the same HCA within one (1) year of leaving, and meet all of the following conditions:
 - (a) The employee completed the HCA's required training and competency assessment at the time of initial employment;
 - (b) The employee successfully completed the HCA'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 from the prior active period of employment is retained in the personnel files.

- (2) An employee moving from one office to another in the same HCA if previous training is documented and the offices have the same orientation and training procedures.
 - (a) Evidence of completed initial orientation and training and competency evaluation must be maintained by each separately licensed HCA.
- (3) A personal care worker 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 HCA shall provide orientation and perform a competency evaluation to ensure the personal care worker is able to differentiate and appropriately perform all personal care worker tasks.

7.6 Training, Competency, and Skills Validation Documentation

- (A) All training, competency, and skills validation shall be documented by the HCA.
 - (1) Documented evidence of trainings, competency testing, and skills validation shall be documented with the date of training; length of training; entity or instructor(s) that offered or produced the training; a short description of the content; and staff member's written or electronic signature or proof of attendance.
 - (2) The HCA shall maintain evidence of training, competency testing, skills validation, and related certificates along with proof of completion in each individual's personnel file.

7.7 Supervisor of Homemakers and Personal Care Workers

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

7.8 Supervision of Homemakers and Personal Care Workers

- (A) Supervision of a homemaker or personal care worker shall:
 - (1) Be performed by an employee of the HCA qualified as a supervisor under Part 7.7, who is in a designated supervisory capacity and available to the worker at all times care and services are being provided;
 - (2) Occur at a minimum of every three (3) months and must include an assessment of consumer satisfaction with services and the worker's competence and adherence to the service plan.
 - (a) Supervision shall be conducted either in person or via telehealth, in accordance with Telehealth Supervisory Visits at Part 7.9(A)(1); and

- (3) Occur, in person, annually for evaluation of each worker providing services in a consumer's home and shall include observation of tasks performed and relationship with the consumer.
- (B) Evidence of all supervisory activities must be documented and retained in the consumer's record. Documentation shall include:
 - (1) The date, time, method of delivery, and location of the supervisory activity along with documentation of persons present;
 - (2) Specific tasks evaluated and/or observed along with outcome; and
 - (3) Information on any re-training, instruction, or other support provided during the supervisory activity.
- (C) An in-person supervisory visit is required to evaluate consumer complaints related to the delivery of care by staff when such concerns cannot be successfully addressed remotely through an interactive audiovisual connection.

7.9 Telehealth Supervisory Visits

- (A) With the exception of the annual supervision requirement in Part 7.8(A)(3) and responding to consumer complaints in Part 7.8(C), The HCA may conduct supervisory visits using telehealth, so long as the HCA continues to ensure consumer care and treatment are delivered in accordance with the service plan that addresses the consumer's status and needs.
 - (1) The designated supervisor may evaluate the delivery of care and services required every three (3) months at Part 7.8(A)(2) through an interactive audiovisual connection with the homemaker or personal care worker and consumer. The results of the supervisory visit must be documented by the qualified employee.
- (B) All other general requirements for supervisory visits, such as documentation and meeting the same standard of care, must be met.

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 Chapter 04 or 6 CCR 1011-1 Chapter 18.

History

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Rules 5.2(A), 5.2(f), 5.4.7(A), 5.4.8 (A) eff. 07/30/2010.

Rule 5.4.8 eff. 09/30/2011.

Rule 5.4 eff. 03/01/2012.

Rules 5.4.4-5.4.7 eff. 03/02/2014.

Rule 5.4.3 eff. 08/14/2014.

Rules 3.6, 3.15-3.28, 5.1(B)-5.1(B)(1), 7.8(B)(1), 7.8(C)(2)-7.8(C)(3), 7.9(A)(1)-7.9(A)(2), 7.9(B)(6)-7.9(B)(7)(b), 7.10(A), 7.10(C)(1), 7.12(A), 7.12(E), 7.13, 8.5(B)(1), 8.5(D)(20), 8.5(E)(1) eff. 09/14/2014.

Rules 3.6, 3.11(B)(8)-3.32, 4.1-4.8(B)(2), 5.2(D), 6.3, 6.7(B) eff. 06/14/2014.

Rules 5.1-5.1(B)(1)(b), 8.5(D)(17)(a), 8.5(D)(17)(b), 8.5(D)(20), 8.5(E)(1) eff. 05/15/2016.

Rule 5.1(A) eff. 01/14/2017. Rule 8.5(B)(1) repealed eff. 01/14/2017.

Rules 5.4.6(A), 5.4.7(A), 6.10(A), 6.14(A) eff. 01/14/2020.

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