

Residential Facilities

1. The requirements contained in this chapter apply only to process, policies and procedures that address those consumers receiving healthcare and/or personal care services in the in their place of residence as directed by the physician or intermediate care provider.
2. The requirements under the licensure classifications apply to all residential facilities providing home care services not covered under its primary residential care license.
 - (a) Any residential care home not licensed as a residential care facility and is providing personal or health care services to its residents or other consumers for a fee (either separately or in the total rate billed) shall be licensed under this chapter.
 - (b) 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 their choice and must not be restricted to the use of the residential facility home care agency.
 - (c) A residential facility may not contract for nor provide health and 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.
3. 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.

The home care records shall be easily identifiable and separated in the consumer record from the residential care records.

ALL: Business Practices

The HCA shall follow appropriate business practices in its care, treatment, and services.

(a) A person designated as compliance officer shall ensure business practices are implemented and effective to guard against fraud and abuse and ensure accurate accounting and billing practices.

(b) Marketing materials shall accurately represent the HCA and address the care, treatment, and services that the HCA can provide directly or through contractual arrangement.

(c) The effectiveness and safety of care, treatment and services shall not depend on the payer source.

(d) The HCA shall manage revenues and expenses on an ongoing basis, including the reconciliation of charges to consumers for equipment, supplies, and services with invoices, receipts, and deposits and tracking actual revenues and expenses.

(e) The HCA shall provide accurate and truthful information to the Department during inspections, investigations and license processing activities. Falsification includes fabrication, in whole or in part, the knowing delivery of inaccurate information orally or in writing, and the failure to provide information requested and known to the agency.

All: Governing Body

(A) A home care agency shall have an organized governing body, or, if a subdivision of a public or private agency or a multifunction organization, a clearly defined local body having legal responsibility for the conduct of the home health agency.

(1) The body shall consist of at least three members who have business and healthcare experience sufficient to oversee the services provided by the home care agency.

(2) At least one member shall be a Colorado resident and one member shall be neither an owner, employee, nor contractor for consumer care services.

(B) The governing body shall have a process for review of agency operations at least quarterly and meet at least annually.

(C) The governing body shall assume responsibility for:

(1) Compliance with all federal regulations, state rules, and local laws;

(2) Quality patient care;

(3) Policies and procedures which describe and direct functions or services of the home care agency and protect patient rights;

(4) Bylaws which shall include at least:

(i) A statement of purpose;

(ii) A statement of qualifications for membership and methods to select members of the governing board;

(iii) A provision for the establishment, selection, and term of office for committee members and officers;

(iv) A description of functions and duties of the governing body, officers, and committees;

(v) A statement of the authority and responsibility delegated to the administrator;

(vi) Meet as stated in bylaws, at least annually;

(vii) Appoint by name and in writing a qualified administrator who is responsible for the agency's overall functions.

(5) Review of the written agency evaluation report and other communications from the administrator or group of professional personnel and provide written directives and comments. Documentation of these reviews shall be signed, dated and available to the Department upon request.

(6) Adequate provision for resources and equipment to provide a safe and effective working environment for personnel and ensure patient safety and welfare.

(7) Establish and ensure the maintenance of a system of financial management and accountability.

(8) Appropriate structure for information management systems including capturing, storing, retrieving, processing, and analyzing data and information. Such procedures shall be included in agency policy and procedure.

(9) Maintain an organizational chart with a written description of the organization, authorities, and responsibilities.

All: Information Management

1. Each HCA shall implement an effective information management system either paper-based or electronic. Processes shall include effective management for capturing, reporting, processing, storing and retrieving clinical/service data and information.

The system shall provide for:

- (a) Timely and easy access to complete information throughout the HCA;
- (b) Data accuracy and security, including maintenance of data integrity;
- (c) Privacy and confidentiality.
- (d) Policies and procedures that allow only authorized staff to gain access to data and information to sensitive consumer, staff and other information

2. Consumer Care and Service Information:

Consumer information shall be readily accessible, accurate, complete, organized for retrieval of data, and timely. The record shall contain sufficient information to identify the consumer; support the diagnosis or condition; justify the care, treatment, and/or services; and promote continuity of care internally and externally where applicable. Such records shall contain consumer-specific information as appropriate to the care, treatment or services provided.

(a) Each HCA shall have a complete and accurate record for each consumer assessed, cared for, treated or served including:

(i) Demographic information – Name, sex, address, phone number, and date of birth; name of any legally authorized representative, and the name and telephone number of a person to be contacted in the event of emergency or death; name, address, phone number of primary physician, nurse practitioner or physician assistant; and the consumer's language and communication needs.

(ii) Source of Referral including individual/agency/facility name, name and phone number of contact, and specific request or orders, and when services are requested to begin.

(iii) Consumer's reason for admission and related health

(iv) Consumer's functional status related to care, treatment or services

(v) Service plan or Plan of Care

(vi) Record of each visit with the consumer. Encounter or Clinical notes shall include date and time visit was initiated and terminated, and documentation at the point of service regarding specific care and/or services provided.

(vii) Records of communications with the consumer regarding care, treatment and services, including documentation of phone calls and emails.

(viii) Supervisory visits including date, time, and whether the paid care giver was present at the home at the time of the visit.

(ix) Communication with the consumer's physician and other care providers (where applicable)

(x) Names of known home care agencies, individuals and organizations involved in the consumer's care

(xi) Documentation received from transferring agencies or facilities;

(xii) Referrals to internal or external care providers and to community services or agencies

(xiii) Consents, statements, disclosures, including but not limited to patient rights, employment disclosures, financial responsibility, consent to treatment or services and advance directive information.

---In addition, home healthcare records shall contain:

(i) Comprehensive assessments, and health professional evaluations.

(ii) Documentation of the home's adaptability or suitability for the specific care, treatment and services to be provided.

(iii) Hospital and emergency room records for episodes occurring just prior to admission if referral is received from the hospital and for episodes occurring after admission.

(iv) 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.

(v) Consumer and family education, and training on the use of equipment at the time of delivery to the home.

(vi) Written summary reports.

(vii) Safety measures taken to protect the consumer from harm and documentation why any identified or planned safety measures were not implemented or continued.

(viii) Allergies or sensitivities

(ix) Medication list including current prescription and non-prescription medications, herbal products and home remedies. The information shall include dose, frequency, and route of administration; with on-going updates including new, changed and discontinued medications and evidence of review for compliance, effectiveness, drug interactions and adverse effects.

(x) Known diagnostic and therapeutic procedures, treatments, tests and their results

(xi) Nutrition, medical diets or dietary restrictions

(xii) Discharge and transfer summaries including documentation of coordination with receiving agencies or facilities

(c) Information is organized according to written policy and procedure.

(d) Capture, storage and retrieval processes shall be designed to provide for timely access without compromising data and protection of data from accidental or unauthorized use.

(i) Documentation of care and services shall be conducted at point of service either on paper or electronically. If the initial paper documentation is on paper and later added to an electronic record, the original paper version shall be retained as the original record or shall be scanned, in whole, into the electronic record.

(ii) Documentation shall be added to the permanent consumer record no more than 10 calendar days after the delivery of care or services.

(e) Agency approved standardized formats shall be utilized for documenting all care, treatment and services provided to consumers. Standardization shall not include the pre-documentation of care and services to be provided.

(f) Entries include date, time, author, discipline (if applicable) and are authenticated either by written or electronic signature.

(e) Policies and processes shall safeguard the consumer record from loss, destruction or tampering and include at minimum:

(i) Policies directing when the removal of records is permitted

(ii) Protection from unauthorized intrusion, corruption, damage, destruction or loss

(iii) Minimize the risk of falsification of data and information

(v) Policies guiding the appropriate destruction of copies and original records

(f) Systems are designed to reduce inaccessibility of the consumer record, data is transformed into standard formats to meet user needs and provide for retrievability and interpretation.

For electronic records, policies and procedures must be devised and implemented to ensure:

(i) data integrity or protection of the data from accidental or unauthorized use.

(ii) Authentication or the validation of correctness for both the information itself and the person who is the author or user of information.

(iii) Non-repudiation or the inability to dispute a document's content or authorship

(iv) Encryption – the process of transforming readable text into cipher text that is unreadable without a special software key.

(v) Audit- ability or the ability to do a methodical examination and verification of all information activities such as entering and accessing.

(vi) recovery of records including contingency plans for operational interruptions (hardware, software, or other systems failures), emergency service plan, a back-up system (electronic or paper), and retrieval of data from storage and information presently in the operating system. The record recovery plan shall be tested at least annually to ensure business interruption back-up techniques are effective.

All: License Classification

(A) A home care agency shall be assigned a license classification consistent with the type and extent of services provided. The Department shall determine the license classification for each HCA applicant based upon the following criteria:

Class A – an agency that provides skilled nursing service and at least one other therapeutic service such as physical, speech or occupational therapy; medical social service or home health aide service. Anyone licensed as Class A shall meet and maintain compliance with the federal requirements for certification as a home health agency. The Class A license includes all other home care classifications (Class B and Class C) for all services provided through the same physical address or in an approved branch location.

Class B – an agency that provides one or more professional home care services, but does not meet certification requirements or wish to seek certification federal certification for home care services. In addition to listed Class A services, a HCA may provide as a single service or in combination: wound care, infusion services, respiratory therapy, case management which includes in-home visits or care, in-home x-ray and diagnostic services, and other in home services requiring either care or oversight by a health professional.

Class C – an agency that provides in-home services including personal care services, in-home support services, independent living skills services or other services in the place of the consumer's residence meets and maintains compliance with state home and community based waiver (HCBS) certification requirements for such programs. The license includes services provided under the Class D license.

Class D- an agency that provides personal care services in the place of residence of the consumer. Services provided do not require an order or supervision from a health professional.

A primary license may be further designated with the sub-classification below:

Subclass 1 – PACE and all-inclusive care programs that are not licensed as another entity, but only a portion of the total services provided are related to home care. This subclass must meet the requirements for the license class unless alternate requirement are addressed under [PACE section].

Subclass 2 – licensed residential facilities providing services outside the provisions of their primary license and in the home of the consumer. This subclass must meet the primary class license unless alternate requirements are addressed under [residential facility section].

(B) When an HCA adds category of service, the agency shall notify the Department. The Department shall then request from the agency the appropriate information needed to determine if the agency meets the regulatory requirements for the category of service being requested. Once this determination is made, the Department shall make the appropriate changes to the license.

(C) If an HCA discontinues a category of service, the agency shall notify the Department. Notification shall include information on how the agency will ensure appropriate transfer of the affected home care consumers.

(D) Each agency that is licensed Class A, B,C, or D shall met the general requirements section of these regulations. According to services provided, each agency shall also be required to meet the specific requirements for skilled care and/or personal care.

All: Transfer of License

No license shall be transferred from one location to another without prior approval from Department as provided in this subsection. If an agency is considering relocation, the agency shall complete and submit a form provided by Department 30 days prior to the intended relocation.

1. A relocation shall be approved if the new location is within the existing geographic service area and the agency continues to serve the same consumer base, and retains the same employees.

2. All other relocations shall not be approved, and the licensee shall submit a new application for a license.

Medical: Administrator

The administrator who is an employee of the agency or related institution, who assumes over-all day-to-day authority for the operation of the agency including but not limited to:

- (a) Organizing and directing the agency's ongoing functions;
- (b) Maintaining an ongoing liaison between the governing body and the personnel;
- (c) Employing qualified personnel and ensure appropriate ongoing education and supervision of personnel and volunteers;
- (d) Ensuring the accuracy of public information materials and activities;
- (e) Implementing a budgeting and accounting system; and
- (f) Ensuring the presence of an alternate administrator to act in the administrator's absence.

Medical: Agency Evaluation

- (a) The agency's governing body or its designee shall, at least annually, cause a comprehensive evaluation of the agency's total operation to be conducted.
- (b) The evaluation shall assure the appropriateness and quality of the agency's services with findings used to verify policy implementation, to identify problems, and to establish problem resolution and policy revision as necessary.
- (c) The evaluation shall consist of an overall policy and administration review, including the scope of services offered, arrangements for services with other agencies or individuals, admission and discharge policies, supervision and plan of care, emergency care, service records, personnel qualifications and program evaluation. Data to be assessed shall include at a minimum the following:
- (1) number of clients receiving each services;
 - (2) number of visits or hours for each service;
 - (3) client outcomes;
 - (4) adequacy of staff to meet client needs;
 - (5) numbers and reasons for nonacceptance of clients; and
 - (6) reasons for discharge;
 - (7) complaints received;
 - (8) occurrences;
 - (9) consumer input and comments;
 - (10) quality assurance data, actions, and outcomes
- (d) In evaluating each aspect of its total program, the HCA should have considered four main criteria:
- (1) Appropriateness - Assurance that the area being evaluated addresses existing 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 accomplishes the objectives of the HHA and anticipated consumer outcomes.
 - (4) Efficiency - Whether there is a minimal expenditure of resources by the HHA to achieve desired goals and anticipated consumer outcomes.

(e) Documentation of the annual evaluation shall include the names and qualifications of the persons carrying out the evaluation, the criteria and methods used to accomplish it, and any action taken by the agency as a result of its findings.

(f) An evaluation of the agency's client records shall be carried out at least quarterly by appropriate professionals representing the scope of the agency's program. The evaluation shall include a review of sample active and closed client records to ensure that agency policies are followed in providing services, both direct and under arrangement, and to assure that the quality of service is satisfactory and appropriate. The review shall consist of a representative sample of all home care services provided by the agency.

Medical: Availability of RN / Therapist

1. The agency shall have a registered nurse or therapist (if nursing is not the predominant service) available after hours. A licensed practical nurse, physical therapy assistant, or certified nurse aide may take initial call and perform services as ordered on the plan of care. If the contact suggests a substantial change in condition, the registered nurse or therapist shall conduct an assessment and intervene on behalf of the consumer. Any services outside the plan of care must be approved by a registered nurse or therapist prior to the services being rendered.

2. The agency shall have a policy describing at least the following:

(a) How patients will contact the agency after hours; and

(b) How the agency will ensure the health professional on call has access to all current patient information.

Medical: Care and Services

1. An initial assessment shall be completed in the consumer's residence by an employee of the agency who has completed orientation/training in the initial assessment procedures of the agency and has demonstrated competency in the performance of these skills. The initial assessment shall be completed by a registered nurse or licensed therapist, as appropriate.
2. At the time of the admission, the plan of care shall be developed in conjunction with the consumer and/or family and the appropriate health care professional.
3. The plan of care shall include potential services to be rendered; the frequency of visits and/or hours of service, assignment of health care providers and the estimated length of services. The plan of care shall be revised at least every 60 days. The plan of care shall be individualized according to each of the individual consumer's needs.
4. The plan of care and each verbal order obtained shall be signed by the physician, or licensed practitioner within 10 days of the receipt of the order.
5. Case conferences shall be held at least every month on each consumer. The minutes of these case conferences shall reflect discussion and input by all the disciplines providing care to the consumer.

Medication Management

1. For consumers receiving medication administration services or extended care nursing services, a current medication administration record shall be maintained and incorporated into the clinical record. Notation shall be on the administration record of medications given; medications not given and reason; medications given according to a sliding scale including the measurement and dose given; and medications given PRN or as needed and the reason given. The nurse or therapist administering medication shall monitor for effectiveness, interactions, and adverse effects.

2. Agencies shall have a written policy stating how controlled drugs will be monitored if agency staff transports the drugs from the pharmacy to the consumer.

3. If controlled drugs are being administered by the agency, there shall be a policy regarding how the drugs will be administered and monitored.

4. If the plan of care includes medication administration, medication management or medication set-up, there shall be documentation as to who is responsible to monitor the medication supply, order refills, and ensure the timely delivery of medications. There shall be evidence that the plan has been discussed and approved by the consumer.

Medical : Discharge Planning

1. There shall be a specific plan for discharge in the clinical record and there must be ongoing discharge planning with the consumer.
2. If no improvement or no discharge is expected, the agency shall document in the clinical record this assessment and the reason why.

Medical: Extended Care

Extended Care is defined as six or more hours of home health services provided in a 24 hour period, by a licensed agency which provides skilled health services. In addition to meeting the applicable standards for a Class A or B license, all agencies providing extended care must meet the following:

A. The agency shall be responsible for assuring that each consumer, or legal representative, is aware of the steps to take in an emergency or unusual situation. The agency must have a contingency plan regarding how the case is managed if a scheduled employee is unable to staff the case;

B. The consumer's permanent medical record shall be available at the licensed agency location;

C. A medical record must also be maintained in the home if a consumer is receiving skilled extended care.

1. The record must contain:

(a) Current plan of treatment (physician's or licensed practitioner orders);

(b) Medication profile;

(c) Clinical notes, containing consumer status or service documentation at least every hour;

(d) Documentation of any medication administered by agency staff including the date, time, dosage and the manner of administration;

(e) Any other information deemed necessary by the licensed agency.

2. The information included in the home record must be filed in the permanent medical record at least every two weeks.

3. If extended care certified nurse aide service is the only service being provided, a home record is not required. Written instructions must be maintained in the home and in the permanent record;

D. The agency must have an orientation plan for the staff providing the care to the consumers. Since extended care cases may involve highly technical services, this plan must reflect how the agency ensures that the individuals providing the extended care are qualified to provide these types of services.

E. Contracting for Extended Care Services

A licensed home health agency may contract with another entity to provide extended care in the licensed agency's service area provided that administration, care and supervision down to the consumer care level is ultimately the responsibility of the licensed agency. The contract must be in conformance to [contract section]. The contracted staff must have completed the agency orientation and competency appraisal for provisions of care and services for the extended care consumer. staff credentialing, orientation, and competency appraisal documentation shall be kept at the primary agency.

F. Conditional Emergency Service

1. The Department shall be approve the provision of extended care to one or more individuals by any licensed extended care provider where such provider:

(a) Certifies that the consumer requires conditional emergency services which shall be defined as; a medically indicated skilled extended care case in which the consumer requires specialized care of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, not available through licensed agencies in the area and which, if not provided, would result in the consumer being institutionalized;

(b) Furnishes information on forms prescribed by the Department regarding the consumers receiving conditional emergency services that include but is not limited to:

(1) Name of consumer;

(2) Address of the consumer;

(3) Diagnosis;

(4) The type of specialized skilled extended care the consumer requires and why the consumer would require institutionalization if the care was not provided;

(c) Furnishes information to the Department ensuring that all agencies whose extended care licensed area encompasses the location of the consumer were contacted to determine if the required services could be provided. Such information should include the name of the agency contacted, the name of the person contacted, the date and time of the contact, and the reason given for not being able to provide the care. If the agency contacted does not respond with an answer within 24 hours of the initial contact, the agency seeking to provide the services may proceed as required. The lack of response should be noted in the information furnished to the Department.

2. Following initial approval, if local services become available, the choice of transfer shall be the consumer/caregiver's decision.

3. An agency operating outside their licensed geographic area to provide approved extended care may provide all services required by the consumer until such time the skilled extended care is discontinued or the consumer is transferred to an agency licensed to provide extended care services in the area.

G. Prior to withdrawing skilled nursing or certified nurse aide services for an extended care consumer the home health agency shall:

1. Show continuing and documented effort to resolve conflicts unless the safety of staff is placed at risk;
2. Provide evidence that ongoing efforts were made to recruit staff or place with another agency; and
3. Give the consumer/family at least 30 days notice, in writing, of the intent to discharge the consumer.

Medical: Training of Staff

(A) Ongoing training shall be provided to all direct care staff. Training shall consist of at least 12 hours every 12 months after the starting date of employment or calendar year as designated by agency policy. The training requirement shall be prorated in accordance with the number of months the employee was actively working for the agency. At least 4 hours annually shall be training that builds upon basic skill levels for each discipline.

Training shall include, but is not limited to, the following items:

- (1) Promoting consumer dignity, independence, self-determination, privacy, choice and rights; including abuse and neglect prevention and reporting requirements.
- (2) Dealing with difficult people including behavioral management techniques for cognitively disabled individuals.
- (3) Disaster and Emergency procedures.
- (4) Hygiene and infection control including universal precautions.
- (5) Nutrition and hydration.
- (6) Basic home safety
- (7) Specialized procedures or care
- (8) Advanced assessment techniques
- (9) Scope and standards of practice

(B) All training shall be documented. Classroom type trainings shall be documented with the date of the training; starting and ending times; instructors and their qualifications; short description of content; and staff member's signature. On-line or self-study trainings shall be documented with information as to the content of the training; and the entity that offered or produced the training. All training documentation shall include a copy of any quiz or other comprehension tool to show the employee understood and properly applied the training presented.

Medical: Professional Advisory Committee

(A) A group of professional personnel, shall include at least one physician and one registered nurse, and a representative from each professional discipline the HCA includes in its policy, and/or information provided to consumers or the Department as services provided to consumers. The group of professional personnel shall establish and annually review the agency's policies governing the all services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group shall be neither an owner, an employee nor a contractor for the provision of consumer care services for the HCA.

(B) The agency shall implement an on-going mechanism for consumer involvement to provide input and comment regarding services provided by the agency in accordance with agency policy. The policy shall include a provision that the consumer has the right to submit comments anonymously and without fear of reprisal. The agency shall inform the consumer of the mechanism to provide input and comments to the agency, and how this mechanism differs from filing a complaint with the agency, including the expectations for follow-up and agency response to consumer input. Consumer input and commentary shall be provided to the group of professional personnel at least annually in the original form and format received by agency and in an aggregate form to identify negative trends or issues requiring consideration of the group.

(C) The group of professional personnel shall meet annually and as frequently as necessary to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program. The HCA shall have a policy and procedure to establish criteria for calling a meeting of the group of professional personnel more frequently than annually and such policy shall be based on, at minimum, increase in number of consumer complaints, severity of consumer complaints, trends or issues identified from consumer input, addition or deletion of service lines or disciplines, coordination issues, events related to consumer harm or potential for harm, issues identified in the quality assurance process requiring correction. The policy shall be developed to ensure professional advice is requested and received at an appropriate frequency to protect and preserve the health, safety, and welfare of the consumers it serves. Each meeting shall be documented by dated minutes and signatures of attendees. Meeting minutes shall be forwarded to the governing body to review and make recommendations.