ACHC STANDARDS

PROGRAM

DMEPOS

SERVICES

Home/Durable Medical Equipment Services

ACCREDITATION STANDARDS PACKET

DMEPOS

Effective Date of DMEPOS Standards: February 1, 2025.

ACHC is committed to providing healthcare organizations with comprehensive standards that facilitate the highest level of performance. To ensure each standard is clear, concise, and relevant, ACHC conducts annual reviews by compiling feedback from providers, industry consultants, and regulatory bodies.

Based on the annual review, ACHC has made the following changes:

- No standards were updated during ACHC's annual review.

The Accreditation Standards Packet contains:

- 2025 ACHC Standards for DMEPOS Accreditation.
- Preliminary Evidence Report (PER) Checklists for DMEPOS (to be used if applying for ACHC Accreditation for the first time).

DMEPOS Distinctions

Distinctions offer additional recognition for organizations that go above and beyond basic accreditation requirements.

Providers accredited by ACHC for Home/Durable Medical Equipment (HME) can choose:

- Distinction in Clinical Respiratory Patient Management (CRPM).

Providers accredited by ACHC for Complex Rehabilitation and Assistive Technology Supplier (RTS) can choose:

- Distinction in Custom Mobility (CM).

PRELIMINARY EVIDENCE REPORT ATTESTATION

DMEPOS

This form must be completed by organizations applying for initial Durable Medical Equipment, Prosthetics, Orthotics, and Supplies [DMEPOS/Community Retail (CR)] accreditation.

Review and acknowledge that all of the following requirements have been met and submit this signed form to ACHC with the items listed below:

- ☐ Accreditation application.
- ☐ Non-refundable deposit.
- ☐ The information packet that is given to the clients/patients when the client/patient is provided equipment, services, or products.
  - » Medicare providers must demonstrate that they are providing beneficiaries with all of the information required in the CMS Quality and Supplier Standards. This would not be applicable to any non-Medicare providers.
  - » It is preferred that this information be provided to ACHC in digital format.
- ☐ Your organizational chart reflecting position titles.

Confirm agreement with the following by initialing in each space provided.

_____ I attest that this organization has written and implemented all policies and procedures required by the ACHC Accreditation Standards.

_____ The organization has **five** client/patient records that demonstrate compliance with Medicare regulations.

- » **If your organization does not have a PTAN,** clients/patients records can be from multiple payor sources such as Medicaid, third-party payors, or cash transactions. *All records must show compliance with the DMEPOS Quality and Supplier Standards.*
- » **If your organization has a PTAN,** and you are applying with ACHC for the first time, a minimum of five Medicare client/patient records are required for survey. *All records must show compliance with the DMEPOS Quality and Supplier Standards.*
  - **You will need to provide a list of all Medicare client/patient records and have them available for the surveyor to randomly select the client/patient records from the list.**

_____ I acknowledge that this organization was/is/will be in compliance with ACHC Accreditation Standards as of _____ (date).

I, having the authority to represent this organization, verify that

_____ (organization's legal name) has met the requirements for survey listed above. I understand that failure to meet any of the aforementioned requirements when the ACHC Surveyor arrives to conduct the survey may result in additional charges to the organization for a subsequent survey to be performed. I agree

that if the organization receives any citation(s) from a federal or state agency while accredited by ACHC, I will notify ACHC within ten (10) calendar days.

Signature: _____ Date: _____

Name: _____ Title: _____

ACHC ACCREDITATION STANDARDS

Customized for Home Medical Equipment Services

Section 1: ORGANIZATION AND ADMINISTRATION

The standards in this section apply to the leadership and organizational structure of the organization. All items referring to business licensure, including federal, state, and local licenses that affect the day-to-day operations of the organization, should be addressed. This section includes information on the organization's leadership structure, including board of directors, advisory committees, management, and employees. Also included is information about leadership responsibilities, conflicts of interest, chain of command, program goals, and regulatory compliance.

Standard DRX1-1A: The organization is an established entity with legal authority to operate and has the appropriate licensure, Articles of Incorporation, or other documentation of legal authority.

The organization is an established entity with legal authority to operate and has the appropriate articles of incorporation or other documentation of legal authority.

Legal authority is granted to one individual, members of a Limited Liability Corporation (LLC), and a board of directors, usually referred to as the governing body, and as allowed in state statutes for the appropriate type and structure of the organization. The entity, individual, or organization has a copy of the appropriate documentation or authorization to conduct business.

If state or applicable local law requires a license or permit, the organization posts the current copy in a prominent location accessible to public view in all locations/branches and/or in accordance with appropriate regulations or laws.

Evidence: Copy of all current applicable license(s)/permit(s) for each location
Evidence: Written Policy and Procedure
Evidence: Observation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-2A: The organization is directed by a governing body/owner (if no governing body is present, owner suffices), that assumes full legal authority and responsibility for the operation of the organization. The governing body/owner duties and accountabilities are clearly defined.

A governing body/owner assumes full legal authority and responsibility for the organization’s management, provision of all services, fiscal operations, and continuous performance improvements that are consistent with acceptable standards of practice. Activities of the governing body/owner include, but are not limited to:

- Decision-making
- Appointing a qualified Administrator
- Establishing or approving written policies and procedures governing overall operations
- Human resource management
- Performance Improvement (PI)
- Oversight of the management and fiscal affairs of the organization
- Review of the policies and procedures during each ACHC accreditation cycle

Although many governing bodies/owners delegate authority for some of these functions to individual personnel members, the ultimate responsibility continues to rest with the governing body/owner. In situations where the Board of Directors serves as the governing body for a large, multi-service organization, board activities will address the overall organization. However, oversight of the organization’s program is documented in some manner, such as in reports to the board or in board meeting minutes.

If the organization has a governing body, the members receive an orientation to their responsibilities and accountabilities. The organization has a list of governing body members that includes names, addresses, and telephone numbers.

Evidence: Board of Directors Meetings Minutes
Evidence: Response to Interviews
Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-3A: Written policies and procedures are established and implemented by the organization in regard to conflicts of interest and the procedure for disclosure.

Written policies and procedures define conflicts of interest and the procedure for disclosure and conduct in relationships with personnel, customers, and clients/patients. The policies and procedures include the required conduct of any affiliate or representative of the following:

- Governing body/owner
- Personnel having an outside interest in an entity providing services to the organization
- Personnel having an outside interest in an entity providing services to the clients/patients

An individual with a conflict of interest is excluded from proceedings that require input, voting, or decision.

Governing board members and personnel demonstrate understanding of conflict-of- interest policies and procedures.

These criteria do not apply to a single owner who serves as the governing body.

Evidence: Written Policies and Procedures
Evidence: Response to Interviews

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-4A: There is an individual who is designated as responsible for the overall operation and services of the organization. The manager/leader organizes and directs the organization's ongoing functions; maintains an ongoing liaison with the governing body/owner and personnel; employs qualified personnel, ensuring adequate personnel education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system.

The manager/leader is responsible for all of the organization's programs and services and is accountable to the governing body/owner. A job description specifies the responsibilities and authority of this individual.

The resume/application of the manager/leader verifies that the individual who holds this position possesses the appropriate education and experience requirements as defined by the governing body/owner and any applicable state and federal laws and regulations.

In the absence of the manager/leader, another individual is authorized, in writing, to act as the manager/leader. The duties this individual assumes during the absence of the manager/leader are written into the individual's job description and are included in the individual’s orientation.

Evidence: Observation
Evidence: Administrator Resume/Application
Evidence: Orientation Records
Evidence: Personnel Files

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-5A: Responsibility and accountability for programs are defined. The organizational chart shows the relationship of all positions within the organization with identifiable lines of authority.

The services furnished by the organization, the administrative control, and the lines of authority for delegating responsibility down to the client/patient care level are clearly defined in writing.

The governing body/owner and all positions are identified on the organizational chart. The organizational chart shows the hierarchy of positions and their related responsibilities for each program or service the organization provides.

Evidence: Organizational Chart
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-7A: The organization is in compliance with all applicable federal, state, and local laws and regulations.

This standard requires compliance with all laws and regulations, including but not limited to:

- Local and state licensure
- The Americans with Disabilities Act (ADA)
- Equal Employment Opportunity Act (EEO)
- Fair Labor Standards Act (FLSA)

- Title VI of the Civil Rights Act of 1964
- Occupational Safety and Health Administration (OSHA)
- U.S. Food and Drug Administration (FDA), if applicable
- Drug Enforcement Administration (DEA), if applicable
- Department of Transportation (DOT), if applicable
- State Department of Agriculture, if applicable
- Medicare regulations
- Medicaid regulations
- Health Insurance Portability and Accountability Act (HIPAA)
- Organization's policies and procedures
- Accreditation Commission for Health Care (ACHC) Accreditation Process
- Other laws and regulations as applicable to the care/service provided

Copies of all required federal and state posters are placed in a prominent location for easy viewing by personnel.

Evidence: Written Policies and Procedures
Evidence: Copies of required Posters in a Prominent Location
Evidence: Observation
Evidence: Personnel Files
Evidence: Patient Records

Services applicable: AIC, CLRM, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-7B: Home medical equipment and supply services are provided in accordance with legal and regulatory guidelines as dictated by local, state, federal laws and regulations.

Home medical equipment and supply services are provided in accordance with accepted ethical and industry standards and in accordance with all applicable local, state, and federal laws and regulations.

Applicable rules and regulations are readily available at all times to appropriate personnel.

Evidence: Access to Applicable Rules and Regulations
Evidence: Observation

Services applicable: CRCS, Fitter, HME, MSP, RTS

Standard DRX1-8A: The organization complies with accepted professional standards of practice.

Accepted standards of practice are utilized by the organization to guide the provision of care/service.

Evidence: Observation
Evidence: Written Policies and Procedures

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-9A: Organizations that provide and bill for services under the Medicare/Medicaid program will comply with the Centers for Medicare & Medicaid Services (CMS) Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier and Quality Standards.

The organization demonstrates knowledge of both CMS DMEPOS Supplier and Quality Standards. Compliance is demonstrated through the implementation of standards in all aspects of the day- to-day operations of the organization.

Evidence: Observation
Evidence: Response to Interviews

Services applicable: AIC, CLRM, CRCS, CRDS, CRTL, Fitter, HME, IRX, IRX-NO797, MSP, RTS, SRX

Standard DRX1-10A: The organization informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from sanctions, regulatory inspections, and/or audits.

Negative outcomes affecting accreditation, licensure, or Medicare/Medicaid certification are reported to ACHC within 30 days. The report includes all actions taken and plans of correction.

Incidents that are reported to ACHC include, but are not limited to:

- License suspension
- License probation, conditions/restrictions to license
- Non-compliance with Medicare/Medicaid regulations identified during survey by another regulatory body
- Revocation of Medicare/Medicaid or third-party provider number
- Any open investigation by any regulatory or governmental authority

Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX1-11A: The organization is in compliance with disclosure of ownership and management information.

The organization discloses the following information to ACHC and other appropriate state or federal agencies at the time of initial application and within 30 days of any change in ownership or management:

- The name and address of all persons with an ownership or control interest of 5 percent or greater
- The name and address of each person who is an officer, a director, an agent, or a managing employee of the organization
- The name and business address of the corporation, association, or other company that is responsible for the management of the organization.
- The name and address of the Chief Executive Officer (CEO) and the Chairman of the Board of Directors of the corporation, association, or other company responsible for management of the organization

Evidence: Observation
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX

Section 2: PROGRAM/SERVICE OPERATIONS

The standards in this section apply to the specific programs and services an organization is supplying. This section addresses rights and responsibilities, complaints, incidents, Protected Health Information (PHI) and compliance with laws to prevent fraud and abuse.

Standard DRX2-1A: Written policies and procedures are established and implemented in regard to the organization's descriptions of care/services and how the information is distributed to personnel, clients/patients, and the community.

Written policies and procedures include, but are not limited to:

- Types of care/service available
- Charges or client/patient responsibility for care/service and/or products before or at time of delivery
- Eligibility criteria
- Hours of operation, including on-call availability
- Contact information and referral procedures

Descriptions of care/services with detailed information are available. Marketing and instructional materials use lay language and provide a more general description of care/services offered.

Clients/patients will receive information about the scope of services that the organization provides prior to or at the time of initiating care/service.

Note: "Documentation provided to the client/patient" is defined as either providing written documentation or written instructions on how to find the information on the organization's website. If the client/patient does not have access to the website or requests a written copy, written documentation is provided to the client/patient, with proof of receipt documented in the client/patient record.

Evidence: Written Policies and Procedures
Evidence: Marketing Materials Including Electronic Media
Evidence: Admission/New Client/patient packet
Evidence: Client/patient Records
Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-2A: Written policies and procedures are established and implemented by the organization in regard to the creation and distribution of the Client/Patient Rights and Responsibilities statement. (Standard DRX2-2A is in regard to the creation and distribution of the statement of the Client/Patient Rights and Responsibilities and the ACHC standard reference next to the client/patient right is the standard that demonstrates the implementation of the client/patient right.)

Written policies and procedures outline the client/patient rights and responsibilities. The organization provides the client/patient with a notice of the client's/patient's rights and responsibilities in advance of furnishing care to the client/patient or during the initial evaluation visit before the initiation of care. The policies and procedures state that if a client/patient cannot read the statement of rights and responsibilities, it is read and a copy given to the client/patient in a language the client/patient understands. For a minor or a client/patient needing assistance in understanding these rights and responsibilities, both the client/patient and the parent, legal guardian, or other responsible person are fully informed of these rights and responsibilities. If required to do so an organization will provide information concerning its Advance Directives prior to providing care/service. Documentation of receipt of the information is maintained in the client/patient record.

The statement of Client/Patient Rights and Responsibilities includes, but is not limited to:

- Be fully informed in advance about care/service to be provided, including the disciplines that furnish care and the frequency of visits, as well as any modifications to the plan of care (DRX2-1A)
- Be informed, in advance of care/service being provided and their financial responsibility (DRX3-4B)
- Receive information about the scope of services that the organization will provide and specific limitations on those services (DRX2-1A)
- Participate in the development and periodic revision of the plan of care (DRX5-4A)
- Refuse care or treatment after the consequences of refusing care or treatment are fully presented (DRX2-6A)
- Be informed of client/patient rights under state law to formulate an Advanced Directive, if applicable (DRX2-6A)
- Have one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality (DRX2-2B)
- Be able to identify visiting personnel members through proper identification (DRX2-2B)
- Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client/patient property (DRX2-3A)
- Voice grievances/complaints regarding treatment or care or lack of respect of property, or recommend changes in policy, personnel, or care/service without restraint, interference, coercion, discrimination, or reprisal (DRX2-4A)

- Have grievances/complaints regarding treatment or care that is (or fails to be) furnished, or lack of respect of property investigated (DRX2-4A)
- Confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information (PHI) (DRX2-5A)
- Be advised on the agency's policies and procedures regarding the disclosure of clinical records (DRX2-5A)
- Choose a healthcare provider, including an attending physician*, if applicable (DRX2-2B)
- Receive appropriate patient-centered care in accordance with physician* orders (DRX2-2B)
- Be informed of any financial benefits when referred to an organization (DRX2-2B)
- Be fully informed of one's responsibilities (DRX2-2B)

When additional state or federal regulations exist regarding the client's/patient's rights, the organization's Client/Patient Rights and Responsibilities statement must include those components. The client/patient has the right to be informed and exercise their rights. If the client/patient has been adjudged incompetent under state law by a court of proper jurisdiction, the rights of the client/patient are exercised by the person appointed to act on the client/patient's behalf. If a state court has not adjudged a client/patient incompetent, any legal representative designated by the client/patient in accordance with state law may exercise the client/patient's rights to the extent allowed by state law.

The organization protects and promotes the exercise of these rights. The organization also develops a statement of client/patient responsibilities.

Personnel are provided training during orientation and at least annually thereafter concerning the organization's policies and procedures on the client/patient rights and responsibilities.

Note: "Documentation provided to the client/patient" is defined as either providing written documentation or written instructions on how to find the information on the organization's website. If the client/patient does not have access to the website or requests a written copy, written documentation is provided to the client/patient, with proof of receipt documented in the client/patient record.

*A physician or other licensed practitioner with prescribing authority

Evidence: Written Policies and Procedures
Evidence: Client/Patient Records
Evidence: Statement of Client's/Patient's Rights and Responsibilities
Evidence: Response to Interviews

Services applicable: AIC, CLRM, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX2-2B: The organization protects and promotes exercising of the client's/patient's rights.

Personnel honor the client/patient right to:

- Have one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality
- Be able to identify visiting personnel members through proper identification
- Choose a healthcare provider, including an attending physician*
- Receive appropriate patient-centered care in accordance with physician* orders
- Be informed of any financial benefits when referred to an organization
- Be fully informed of one's responsibilities

*A physician or other licensed practitioner with prescribing authority

Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX2-2C: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Standards are distributed to each Medicare recipient of care/service provided.

A copy of the DMEPOS Supplier Standards or the CMS approved "notice of the Supplier Standards and where they can be found on line" must be distributed to the client/patient (for Medicare beneficiaries who are receiving equipment and/or supplies under Medicare Part B) with documentation of receipt. This evidence may be provided either by obtaining client/patient signatures or by noting in the client/patient record that the DMEPOS Supplier Standards were provided.

Note: "Documentation provided to the client/patient" is defined as either providing written documentation or written instructions on how to find the information on the organization's website. If the client/patient does not have access to the website or requests a written copy, written documentation is provided to the client/patient, with proof of receipt documented in the client/patient record.

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: AIC, CLRM, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX

Standard DRX2-3A: Written policies and procedures are established and implemented by the organization for reporting and investigating all alleged violations involving mistreatment, neglect, or verbal, sexual, and physical abuse, including injuries of unknown source and misappropriation of client/patient property by anyone furnishing services on behalf of the organization.

The client/patient has the right to be free of mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source and misappropriation of client/patient property.

The organization ensures this right and investigates all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source and misappropriation of client/patient property by anyone furnishing services on behalf of the organization. These are reported immediately to the Administrator or appropriate designee.

The organization immediately investigates all alleged violations involving anyone furnishing services on behalf of the organization and takes action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations are conducted in accordance with established policies and procedures.

The organization takes appropriate corrective action in accordance with state law if the alleged violation is verified by the organization's administration or an outside body having jurisdiction, such as ACHC, the state survey agency, or a local law enforcement agency. The organization ensures that verified violations are reported to ACHC as well as state and local bodies having jurisdiction within five working days of becoming aware of the verified violation, unless state regulations are more stringent.

Evidence: Written Policies and Procedures
Evidence: Incident Reports/Investigation Results
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-4A: Written policies and procedures are established and implemented requiring that, at the initiation of care, the organization informs the client/patient on how to report grievances/complaints and how they are investigated and resolved.

The client/patient has the right to voice grievances/complaints regarding treatment or care that is (or fails to be) furnished and lack of respect of property by anyone who is furnishing care/service on behalf of the organization, and must not be subjected to discrimination or reprisal for doing so.

The organization ensures this right and investigates all grievances/complaints. Written policies and procedures include, but are not limited to:

- The appropriate person to be notified of the grievance/complaint
- Time frames for investigation activities, to include after-hours
- Reporting of information
- Review and evaluation of the collected information
- Communication with the client/patient
- Documentation of all activities involved with the grievance/complaint, investigation, analysis, and resolution

The organization investigates and attempts to resolve all client/patient grievances/complaints and documents the results within a time frame defined in the organization's policies and procedures.

The organization maintains records of grievances/complaints and their outcomes, and submits a summary report to the governing body/owner. This information is included in the Performance Improvement (PI) annual report.

Personnel are oriented and familiar with the client/patient grievance/complaint policies and procedures. Personnel assist in implementing the resolution process when needed.

For pharmacies that receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Written Policies and Procedures
Evidence: Grievance/Complaint Log
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRSRX, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-4B: Within five (5) calendar days of receiving a beneficiary's complaint, a Medicare supplier shall notify the beneficiary using either oral, telephone, e-mail, fax, or letter format, that it has received the complaint and that it is investigating. Within 14 days, the supplier shall provide written notification to the beneficiary of the results of its investigation and response. The supplier shall maintain documentation of all complaints that it receives, copies of the investigations, and responses to beneficiaries.

The organization will maintain records of all grievances/complaints, client/patient notifications, investigations and outcomes, and report these to leadership through the Performance Improvement (PI) committee.

Evidence: Grievance/Complaint Records and/or Files
Evidence: Response to Interviews

Services applicable: AIC, CLRM, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX

Standard DRX2-4C: The organization provides the client/patient with information concerning how to contact the organization, appropriate state agencies, and ACHC concerning grievances/complaints at the time of admission.

The organization provides all clients/patients with information listing a telephone number, contact person, and the organization's process for receiving, investigating, and resolving grievances/complaints about its services/care.

When required by state regulations, the agency advises the clients/patients of the telephone number for the appropriate state regulatory body's hotline, the hours of operation, and the purpose of the hotline. This may be a separate information sheet given to the client/patient or incorporated with the client/patient rights and responsibilities information. ACHC's telephone number must be provided. The ACHC phone number requirement is not applicable to an organization if this is its first ACHC survey.

Note: "Documentation provided to the client/patient" is defined as either providing written documentation or written instructions on how to find the information on the organization's website. If the client/patient does not have access to the website or requests a written copy, written documentation is provided to the client/patient, with proof of receipt documented in the client/patient record.

Evidence: Client/Patient Records
Evidence: Admission/New Client/Patient Packet
Evidence: Policy and Procedure

Services applicable: AIC, CLRM, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-5A: Written policies and procedures are established and implemented by the organization in regard to securing and releasing confidential and Protected Health Information (PHI) and Electronic Protected Health Information (EPHI).

The client/patient has the right to a confidential client/patient record. The organization ensures this right and follows all policies and procedures to secure client/patient information.

Confidentiality policies and procedures include, but are not limited to:

- A definition of PHI and confidential information, and the types of information that are covered by the policy, including electronic information, telephone and cell phone communications, and verbal and faxed information
- Persons/positions authorized to release PHI/EPHI and confidential information
- Conditions that warrant its release
- Persons to whom it may be released
- Signature of the client/patient or someone legally authorized to act on the client's/patient's behalf
- A description of what information the client/patient is authorizing the organization to disclose
- Securing client/patient records and identifying who has authority to review or access clinical records
- When records may be released to legal authorities
- The storage and access of records to prevent loss, destruction, or tampering of information
- The use of confidentiality/privacy statements and who is required to sign a confidentiality/privacy statement

The organization has clearly established written policies and procedures that address the areas listed above are clearly communicated to staff.

There is a signed confidentiality statement for all personnel and the governing body/owner as required in the organization's policies and procedures. Personnel and the governing body/owner abide by the confidentiality statement and the organization's policies and procedures. The organization designates an individual responsible for seeing that the confidentiality and privacy policies and procedures are adopted and followed.

The individual contacting the client/patient for the first time will provide written information and will discuss confidentiality/privacy of client/patient-specific information as included in the Client/Patient Rights and Responsibilities statement. Documentation of receipt of confidentiality information is maintained in the client/patient record. Client/patient records contain signed release of information statements/forms when the organization bills a third-party payor or shares information with others outside the organization as required by the Health Insurance Portability and Accountability Act (HIPAA) and other applicable laws and regulations.

In accordance with the provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, any breaches to confidentiality of client/patient PHI must be investigated and the affected individuals must be notified that their health information was breached.

Evidence: Written Policies and Procedures
Evidence: Signed Confidentiality Agreements
Evidence: Observation
Evidence: Response to Interviews
Evidence: Client/Patient Records

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-5C: The organization has Business Associate Agreements (BAAs) for all business associates that may have access to Protected Health Information (PHI) as required by Health Insurance Portability and Accountability Act (HIPAA) and other applicable law and regulations.

A copy of all BAAs will be on file at the organization for all non-covered entities as defined by HIPAA.

Examples of non-covered entities include, but are not limited to:

- A Certified Public Account (CPA) firm whose accounting services to a healthcare provider involves access to PHI.
- An attorney whose legal services to a health plan involve access to PHI
- A consultant who has access to PHI
- An independent medical transcriptionist who provides transcription services to a physician*

A BAA is not required with persons or organizations (e.g., janitorial service or electrician) whose functions or services do not involve the use or disclosure of PHI and where any access to PHI by such persons would be incidental, if at all.

*A physician or other licensed practitioner with prescribing authority

Evidence: Business Associate Agreements

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-7A: Written policies and procedures are established and implemented by the organization in regard to identification, evaluation, and discussion of ethical issues.

The organization provides care/service within an ethical framework that is consistent with applicable professional and regulatory bodies. Written policies and procedures address the mechanisms utilized to identify, address, and evaluate ethical issues.

Examples of forums utilized to consider and discuss ethical issues include:

- Ethics committee
- Ethics forums
- Professional expert access
- Performance Improvement (PI) committee

The organization monitors and reports all ethical issues and actions to the governing body/organizational leaders as outlined in policies and procedures.

All personnel receive training during initial orientation and annually, that includes examples of potential ethical issues and the process to follow when an ethical issue is identified.

Evidence: Written Policies and Procedures
Evidence: Governing Body Meeting Minutes, if applicable
Evidence: Response to Interviews

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX2-8A: Written policies and procedures are established and implemented by the organization in regard to the provision of care/service to clients/patients with communication or language barriers.

Personnel can communicate with the client/patient in the appropriate language or form understandable to the client/patient. Mechanisms are in place to assist with language and communication barriers. This may include the availability of bilingual personnel, interpreters, or assistive technologies. Personnel can communicate with the client/patient by using special telephone devices for the deaf or other communication aids such as picture cards or written materials in the client's/patient's language.

All personnel are knowledgeable regarding the written policies and procedures for the provision of care/service to clients/patients with communication barriers.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-8B: Written policies and procedures are established and implemented for the provision of care/service to clients/patients from various backgrounds, beliefs, and religions.

Written policies and procedures describe how the organization provides care that reflect a "whole person" approach to each clients/patients and family. The policies and procedures also describe any actions expected for personnel providing care to clients/patients who have different backgrounds, beliefs, and religions.

Client's/patient's lifestyles, habits, approach to health, healing and illness vary. Personnel identify differences in their own beliefs and the client's/patient's beliefs and find ways to support the client/patient. Personnel make efforts to understand how the clients'/patients' beliefs impact their perception of their illness

All personnel are provided with education and resources at orientation and annually to increase their awareness of the specific needs of the clients/patients/families they serve.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX2-9A: Written policies and procedures are established and implemented by the organization in regard to a Compliance Program aimed at preventing fraud and abuse.

The organization has an established Compliance Program that provides guidance for the prevention of fraud and abuse. The Compliance Program identifies and discusses numerous compliance risk areas particularly susceptible to fraud and abuse.

The Compliance Program details actions the organization takes to prevent violations of fraud and abuse. The guidelines include, but are not limited to:

- Implementing written policies and procedures and standards of conduct
- Designating a Compliance Officer (as defined in a job description) and Compliance Committee
- That conducts effective training and education programs
- Developing open lines of communication between the Compliance Officer and/or Compliance Committee and organization personnel for receiving complaints and protecting callers from retaliation
- Performing internal audits to monitor compliance
- Establishing and publicizing disciplinary guidelines for failing to comply with the policies and procedures, applicable statutes, and regulations
- Promptly responding to detected offenses through corrective action

Evidence: Written Policies and Procedures
Evidence: Performance Improvement Activities
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX2-10A: Home Medical Equipment (HME) services are available 24 hours a day, 7 days a week for organizations that provide respiratory equipment, such as oxygen, ventilators, and Continuous Positive Airway Pressure (CPAP) and Respiratory Assist Devices (RAD).

The organization provides home medical equipment services 24 hours a day, 7 days a week as necessary to meet client/patient needs. Properly trained personnel are available for the services provided. A supervisor will be accessible via paging system, answering service, phone, or other means.

Evidence: On-Call Schedule
Evidence: Response to Interviews

Services applicable: HME

Standard DRX2-10C: There is an availability of appropriate personnel during posted hours of operation. There is an answering system to receive calls after-hours.

The organization provides services to meet client/patient needs through posted hours of operation. Appropriate personnel are immediately available during the hours of operations. An answering system or service receives calls after-hours.

Evidence: On-Call Logs
Evidence: Posted Hours of Operation

Services applicable: Fitter, HME, MSP, RTS

Section 3: FISCAL MANAGEMENT

The standards in this section apply to the financial operations of the organization. These standards address the annual budgeting process, business practices, accounting procedures, and the company's financial processes.

Standard DRX3-1A: The organization's annual budget is developed in collaboration with management and personnel and under the direction of the governing body/owner.

There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that an item-by-item identification of the components of each type of anticipated income or expense be prepared in connection with any budget.

The organization has a budget that includes projected revenue and expenses for all programs and care/services it provides. The budget is reflective of the organization's care/service and programs.

The organization's leaders and the individuals in charge of the day-to-day program operations are involved in developing the budget and in planning and review of periodic comparisons of actual and projected expenses and revenues for care/service.

The budget is reviewed and updated at least annually by the governing body/owner and the organization's leadership personnel.

Evidence: Current Annual Budget
Evidence: Observation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX3-2A: The organization implements financial practices that ensure accurate accounting and billing.

These practices include, but are not limited to:

- Receipt and tracking of revenue
- Billing of clients/patients and third-party payors
- Notifying the client/patient of changes in reimbursement from third-party payors
- Collection of accounts
- Reconciling of accounts
- Extension of credit, if applicable
- Financial hardship, if applicable
- Defining consequences of non-payment; if applicable
- Assignment of revenue to the appropriate program
- Retaining of financial records per applicable laws and regulations

Evidence: Observation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX3-4A: The organization develops care/service rates and has method(s) for conveying charges to the client/patient, the public, and referral sources.

Current charges for care/services are available for reference by personnel when conveying information to the client/patient, public, and referral sources.

Personnel responsible for conveying charges are oriented and provided with education concerning the conveying of charges.

Evidence: List of Care/Services with Corresponding Charges

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX3-4B: The client/patient is advised of their financial responsibility for the equipment/service being provided at, or prior to the receipt of the equipment/services. The client/patient also has the right to be informed of changes in payment information as soon as possible but no later than 30 days after the organization becomes aware of the change. Clients/patients who are eligible for Medicare or Medicaid are informed when Medicare/Medicaid assignment is or is not accepted.

The client/patient record contains documentation of the communication to the client/patient in regard to their financial responsibility

and any insurance verification completed by the organization which may include deductibles, copayments, and coverage criteria.

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX3-5A: Financial hardship forms are completed if the client/patient is unable to pay.

Financial hardship forms are completed on all clients/patients if they are unable to pay for the equipment, supplies, drugs (if applicable), or care/services that have been provided. The completion of these forms is coordinated between the organization and the client/patient when needed.

Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX

Standard DRX3-6A: The organization ensures proper billing procedures; this would include any prescription, documentation, or other requirements specified by the payor.

Documentation demonstrates compliance with Medicare, Medicaid, and/or third-party payor requirements specific to the equipment and/or service provided.

For Specialty Pharmacy organizations, electronic claims comply with the National Council for Prescription Drug Program (NCPDP) standard transactions.

Evidence: Client/Patient Records or other documentation
Evidence: Response to Interviews
Evidence: Observation
Evidence: Policy and Procedure

Services applicable: AIC, CLRM, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Section 4: HUMAN RESOURCE MANAGEMENT

The standards in this section apply to all categories of personnel in the organization unless otherwise specified. Personnel may include, but are not limited to, support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory employees, contracted personnel, independent contractors, volunteers, and students completing clinical internships. This section includes requirements for personnel records, including skill assessments and competencies.

Standard DRX4-1A: Written policies and procedures are established and implemented that describe the procedures to be used in the management of personnel files and confidential personnel records.

The written policies and procedures include, but are not limited to:

- Positions having access to personnel files
- Proper storage
- The required contents
- Procedures to follow for employees who wish to review their personnel file
- Time frames for retention of personnel files

The organization has all of its employees' personnel records available for inspection by federal, state, regulatory, and accreditation agencies.

Evidence: Written Policies and Procedures
Evidence: Personnel Files
Evidence: Observation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX4-1B: Prior to or at the time of hire, all personnel will complete the appropriate documentation.

Prior to or at the time of hire, all personnel complete the appropriate documentation that includes, but is not limited to:

- Position application
- Dated and signed withholding statements
- Form I-9 (employee eligibility verification that confirms citizenship or legal authorization to work in the United States)

Evidence: Personnel Files

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX4-1C: All personnel files at a minimum contain evidence of the following items. (Informational Standard Only)

Please refer to the standard listed for a detailed description of these requirements.

Description:	Standard:
Position application	DRX4-1B
Dated and signed Withholding Statements	DRX4-1B
Form I-9 (employee eligibility verification which confirms citizenship or legal authorization to work in the United States)	DRX4-1B
Personnel credentialing	DRX4-2B, DRX4-5A(RTS), DRX1-7E(Fitter), DRX4-5D (CRCS), DRX4-5E (HME), DRX4-5C(HME/Fitter),
Tuberculosis (TB) Screening	DRX4-2C
Hepatitis B vaccination	DRX4-2D
Job description	DRX4-2E
Motor vehicle license, if applicable	DRX4-2F
Criminal background check	DRX4-2H
National sex offender	DRX4-2H
Office of Inspector General (OIG) exclusion list	DRX4-2H
Personnel policies review or employee handbook	DRX4-2I
Annual performance evaluation	DRX4-2J
Verification of qualifications	DRX4-13B(IRN), DRX4-14B(AIC, IRN, IRX, SRX, SRXONLY)
Orientation	DRX4-6A

Confidentiality agreement	DRX2-5A
Competency assessments	DRX4-7A, DRX4-7C
Annual evaluation of job duties	DRX4-7A

- Personnel includes, but is not limited to: support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory personnel, contract personnel, and volunteers
- For contract staff the organization must have access to all of the above items, except position application, withholding statements, I-9 and personnel handbook. The remainder of items must be available for review during survey but do not need to be kept on site
- Direct client/patient care - care of a client/patient provided personally by a staff member or contracted individual/ organization in a client's/patient's residence or healthcare facility. Direct client/patient care may involve any aspects of the health care of a client/patient, including treatments, counseling, self-care, client/patient education, and administration of medication

AIC - Ambulatory Infusion Center
CRCS - Clinical Respiratory Care Services
CRTL- Community Retail
CRDS – Community Retail with Fitter Services
Fitter - Fitter services
HME - Home Medical Equipment
IRN - Infusion Nursing
IRX - Infusion Pharmacy with sterile compounding <797>
IRX-NO797 - Infusion Pharmacy without sterile compounding <797>
RTS – Complex Rehabilitation and Assistive Technology Supplier
SRX - Specialty Pharmacy
SRXONLY - Specialty Pharmacy with no DMEPOS

Evidence: None Required/Informational Standard

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX4-2B: Personnel are qualified for the positions they hold by meeting the education, training, and experience requirements defined by the organization. Personnel credentialing activities are conducted at the time of hire and upon renewal to verify qualifications of all personnel.

Personnel hired for specific positions within the organization meet the minimum qualifications for those positions in accordance with the organization's policies and procedures and job descriptions.

Education, training, and experience are verified prior to employment. This can be accomplished by obtaining copies of resumes, applications, references, diplomas, licenses, certificates, and workshop attendance records.

All clinical professionals who furnish services directly, under an individual contract, or under arrangements with an organization must be legally authorized (i.e., licensed, certified, or registered) in accordance with applicable federal, state, and local laws and must act only within the scope of their state license, state certification, or registration. All personnel qualifications must be kept current at all times.

The personnel file or other personnel records contain validation that credentialing information is obtained at the time of hire and in accordance with specific state practice act requirements.

Credentialing information includes a procedure for the review of professional occupational licensure, certification, registration, or other training as required by state boards and/or professional associations for continued credentialing.

Credentials are verified through the appropriate licensing or credentialing organizations.

For pharmacies that receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Personnel Files

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX4-2C: Written policies and procedures are established and implemented in regard to all direct care personnel having a baseline Tuberculosis (TB) test at any point in the past or in accordance with state requirements. Prior to patient contact, an individual TB risk assessment and a symptom evaluation are completed.

Prior to patient contact, direct care personnel provide or have:

- Upon hire personnel provide evidence of a baseline TB skin or blood test.
- Prior to patient contact, an individual TB risk assessment and symptom evaluation are completed to determine if high risk exposures have occurred since administration of the baseline TB test.
- If there is no evidence of a baseline TB skin or blood test, TB testing is conducted by the organization.

An organization conducts an annual TB risk assessment to determine the need, type, and frequency of testing/assessment for direct care personnel.

Annual TB testing of health care professionals is not recommended unless there is a known exposure or ongoing transmission.

Evidence: Written Policies and Procedures
Evidence: Personnel Files or other Confidential Employee Records

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, RTS, SRX, SRXONLY

Standard DRX4-2D: Written policies and procedures are established and implemented that describe the process for all direct care personnel to have access to the Hepatitis B vaccine as each job classification indicates and as described in federal Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) standards.

The Hepatitis B vaccination program and post-vaccination antibody titer are performed in accordance with CDC and OSHA guidelines. Personnel sign a declination statement for the Hepatitis B vaccination within 10 working days of employment if they choose not to become vaccinated.

The following are circumstances under which an organization is exempted from making the vaccination available:

- The complete Hepatitis B vaccination series was previously received
- Antibody testing shows the employee to be immune
- The vaccine cannot be given to the individual for medical reasons or the individual cannot receive antibody testing

Evidence: Written Policies and Procedures
Evidence: Personnel Files or other Confidential Employee Records

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, RTS, SRX, SRXONLY

Standard DRX4-2E: There is a job description for each position within the organization that is consistent with the organizational chart with respect to function and reporting responsibilities.

The job description lists:

- Job duties
- Reporting responsibilities
- Minimum job qualifications, experience, education, and training
- Requirements for the job
- Physical and environmental requirements with or without reasonable accommodation

The organization's job descriptions are consistent with the organizational chart with respect to function and reporting responsibilities. Review of the job description with personnel is conducted as part of the orientation process and whenever the job description changes. There is documentation of receipt of the job description at orientation and whenever the job description changes (e.g., signed job description, orientation check list, or electronic verification).

For pharmacies that receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Job Descriptions
Evidence: Response to Interviews
Evidence: Personnel Files

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX4-2F: Organizations that use motor vehicles that require a special class of driver's license, such as a Commercial Driver's License (CDL) verify through a Motor Vehicle Records (MVRs) check that the employee has a valid license at time of hire and annually.

There is evidence that all personnel required to have a CDL or other specialized driver's license has an MVR check through the state department of motor vehicles or other state-recognized site at time of hire and annually.

Evidence: Personnel Files

Services applicable: CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX

Standard DRX4-2H: Written policies and procedures are established and implemented in regard to background checks being completed on personnel who have direct client/patient care and/or access to client/patient records. Background checks include: Office of Inspector General (OIG) exclusion list, criminal background record, and national sex offender registry.

The organization obtains a criminal background check, OIG exclusion list check, and national sex offender registry check on all organization employees who have direct client/patient care. Organization contracts require that all contracted entities obtain criminal background check, OIG exclusion list check, and national sex offender registry check on contracted employees who have direct client/patient care.

The organization obtains a criminal background check and OIG exclusion list check on all organization employees who have access to client/patient records. Organization contracts require that all contracted entities obtain criminal background checks and OIG exclusion list check on contracted employees who have access to client/patient records.

Criminal background checks are obtained in accordance with state requirements. In the absence of state requirements, criminal background checks are to be obtained within three months of the date of employment for all states where that individual has lived or worked in the past three years.

The organization has policies and procedures regarding special circumstances, if any, for hiring a person convicted of a crime. The policies and procedures include, but are not limited to:

- Documentation of special considerations
- Restrictions
- Additional supervision

The OIG exclusion list check applies to organizations that accept federal reimbursement dollars, but should preferably be performed for all organizations.

Evidence: Written Policies and Procedures
Evidence: Personnel Files

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX4-2I: Written personnel policies and procedures and/or an employee handbook are established and implemented describing the activities related to personnel management.

Information in the personnel policies and procedures and/or employee handbook includes, but is not limited to:

- Wages
- Benefits
- Complaints and grievances
- Recruitment, hiring, and retention of personnel
- Disciplinary action/termination of employment
- Professional boundaries and conflict of interest
- Performance expectations and evaluations

The personnel policies and procedures and/or employee handbook are reviewed at least annually, updated as needed, and are in accordance with applicable laws and regulations. Personnel policies and procedures show evidence of non-discriminatory practices.

Wages
Information is available on overtime, on-call, and holiday pay, and exempt versus non-exempt status.

Benefits
An explanation of benefits is shared with all eligible personnel. Organizations that provide no benefits to some categories of personnel communicate this fact in writing to affected personnel. For example, the contract/agreement with personnel who are utilized on an "as needed" basis may address that benefits are not available to persons employed in that classification.

Complaints and Grievances
Written grievance information addresses options available to personnel who have work-related complaints, including steps involved

in the grievance process.

Recruitment, Hiring and Retention of Personnel
The organization has written policies and procedures on recruitment, hiring, and retention of personnel that demonstrate non-discriminatory practices.

Disciplinary Action and Termination of Employment
Disciplinary action and termination of employment policies and procedures define time frames for probationary actions, conditions warranting termination, steps in the termination process, and the appeal process.

Professional Boundaries
Written policies and procedures are established and implemented that define professional boundaries.

Conflicts of Interest
Written policies and procedures are established and implemented that define a conflict of interest.

Performance Expectations and Evaluations
The organization's policies and procedures outline general performance expectations of all personnel (e.g., dress code, and professional conduct), along with the schedule for performance evaluations.

Written documentation is kept verifying that the employee has reviewed and has access to personnel policies and procedures.

For pharmacies who receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Written Policies and Procedures and/or Employee Handbook
Evidence: Personnel Files
Evidence: Observation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX4-2J: Written policies and procedures are established and implemented in regard to written annual performance evaluations being completed for all personnel based on specific job descriptions. The results of annual performance evaluations are shared with personnel.

Written policies and procedures are established and implemented addressing individual performance evaluations for all personnel. These policies and procedures describe how performance evaluations are conducted, who conducts them, and when they are to be conducted. The policies and procedures also identify any deviations to their policy.

Personnel evaluations are completed, shared, reviewed, and signed by the supervisor and employee no less frequently than every 12 months.

For pharmacies that receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Written Policies and Procedures
Evidence: Personnel Files
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX4-5C: There is a qualified person responsible for supervision of Home Medical Equipment (HME) and Fitter services.

All HME and fitter services are provided under the direction of a person with sufficient education and experience in the scope of services offered.

Evidence: Observation

Services applicable: Fitter, HME

Standard DRX4-5E: There is an experienced individual responsible for supervising respiratory equipment services.

Respiratory equipment services include the delivery, setup, education, maintenance, and servicing of respiratory equipment. Respiratory equipment includes, but is not limited to:

- Oxygen concentrators
- Reservoirs
- High-pressure cylinders
- Oxygen accessories and supplies
- Oxygen-conserving devices
- Continuous Positive Airway Pressure (CPAP) devices
- Respiratory Assist Devices (RAD)
- Nebulizers
- Home mechanical ventilator
- Intermittent Positive Pressure Breathing Device

Organizations providing respiratory equipment services are supervised by an individual with extensive experience with respiratory equipment and related uses of the equipment.

Organizations follow state regulations when the requirements dictate who can deliver, setup, educate, and supervise respiratory equipment services.

Organizations comply with American Association of Respiratory Care (AARC) Practice Guidelines for respiratory care therapies in the home.

Evidence: Personnel Files
Evidence: Observation

Services applicable: Fitter, HME, MSP

Standard DRX4-6A: Written policies and procedures are established and implemented that describe the orientation process. Documentation reflects that all personnel have received an orientation.

The orientation policies and procedures include, but are not limited to:

- Review of the individual's job description, duties performed, and the individual’s role in the organization
- Organizational chart
- Record keeping and reporting
- Confidentiality and privacy of Protected Health Information (PHI)
- Client's/patient's rights
- Advance Directives, if applicable to the service(s) provided
- Conflict of interest
- Written policies and procedures
- Emergency plan
- Training specific to job requirements
- Additional training for special populations, if applicable (e.g., nursing homes, pediatrics, or disease processes with specialized care)
- Patient-specific needs
- Communication barriers
- Ethical issues
- Professional boundaries
- Performance Improvement (PI) Plan
- Compliance Program
- Conveying of charges for care/service
- Occupational Safety and Health Administration (OSHA) requirements, safety, and infection control
- Orientation to equipment, if applicable as outlined in job description
- Incident/variance reporting
- Handling of client/patient complaints/grievances
- ACHC Accreditation Standards

The organization creates and completes a checklist or other methods to verify that the topics have been reviewed with all personnel.

For pharmacies that receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Written Policies and Procedures
Evidence: Personnel Files
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX4-7A: Written policies and procedures are established and implemented requiring the organization to design a competency assessment program on the care/service provided for all personnel who set up, train, clean, test, repair, and/or educate on the use of medications, equipment, and/or supplies.

The organization designs and implements a competency assessment program based on the care/service provided for all personnel who set up, train, clean, test, repair, and/or educate on the use of medications, equipment, and/or supplies. Competency assessment is an ongoing process and focuses on the primary care/service being provided and is conducted initially during orientation, prior to providing a new task, and annually thereafter. Validation of skills is specific to the employee's role and job responsibilities.

Policies and procedures for determining that personnel who set up, train, clean, test, repair, and/or educate on the use of medications, equipment, and/or supplies are competent to provide quality care/service are in place and may be accomplished through observation, supervisory visits, knowledge-based tests, and self-assessment. All competency assessments and training are documented. A self-assessment tool alone is not acceptable. Peer review of clinical personnel competency by like disciplines is acceptable if defined by the organization. There is a plan in place for addressing performance and education of personnel when they do not meet competency requirements.

For pharmacies that receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Written Policies and Procedures
Evidence: Competency Assessment

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX4-8A: A written education plan is developed and implemented that defines the content, frequency of evaluations, and amount of ongoing in-service training for each classification of personnel.

The education plan includes training provided during orientation as well as ongoing in-service education. Organizations provide this training directly or arrange for personnel to attend sessions offered by outside sources.

The ongoing in-service education plan is a written document that outlines the education to be offered for personnel throughout the year. The plan is based on a reliable and valid assessment of needs relevant to individual job responsibilities. Education activities also include a variety of methods for providing personnel with current relevant information to assist with their learning needs. These methods include provision of journals, reference materials, books, internet learning, in-house lectures, and demonstrations, and access to external learning opportunities.

The organization has an ongoing education plan that annually addresses, but is not limited to:

- Emergency/disaster training
- How to handle grievances/complaints
- Infection control training
- Patient-specific needs
- Communication barriers
- Ethics training
- Workplace (Occupational Safety and Health Administration [OSHA]), client/patient safety, and components of DRX7-2A
- Client/patient rights and responsibilities
- Compliance Program

There is written documentation confirming attendance at ongoing education programs.

For pharmacies that receive ACHC Community Retail Accreditation, this standard only applies to personnel who provide Community Retail-accredited product codes.

Evidence: Written Policies and Procedures
Evidence: Response to Interviews
Evidence: Training/In-service Logs

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX4-11C: An organization that uses outside personnel to provide care/services on behalf of the organization has a written contract/agreement for care/services that is kept on file within the organization.

Arranged care/services are supported by written agreements that require that all care/services are:

- Authorized by the organization
- Furnished in a safe and effective manner by qualified personnel/organizations

Organizations that utilize personnel/organizations on an hourly or per visit basis have a written contract/agreement that includes, but is not limited to:

- The care/services to be furnished
- Compliance with organizational policies and procedures, including personnel qualifications, orientation, competencies, and required background checks
- Responsibilities of each party
- The manner in which care/services will be controlled, coordinated, and evaluated by the primary organization
- The procedures for submitting documentation
- Procedures for the payment, including the amount, for care/services furnished under the contract
- Duration of contract/agreement
- Overall responsibility for supervision of personnel
- Other applicable laws and regulations

In addition, the organization maintains current copies of professional liability insurance certificates for all contract personnel/organizations providing direct care/service and/or other organizations providing shared responsibility for care/service. If the organization provides the liability insurance for contract personnel, it is evidenced in the organization's insurance policy.

The organization has an established process to review and renew contract/agreements as required by the contract.

Evidence: Written Contracts/Agreements
Evidence: Professional Liability Insurance Certificates

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Section 5: PROVISION OF CARE AND RECORD MANAGEMENT

The standards in this section apply to documentation and requirements for the service recipient/client/patient/resident record. These standards also address the specifics surrounding the operational aspects of care/services provided.

Standard DRX5-1A: Written policies and procedures are established and implemented relating to the required content of the client/patient record. An accurate record is maintained for each client/patient.

Written policies and procedures define the required content of the client/patient record. The content includes, but is not limited to:

- Identification data
- Names of family/legal guardian/emergency contact
- Name of primary caregiver(s)
- Name of physician* responsible for care
- Diagnosis
- Physician's* orders
- Signed release of information and other documents for Protected Health Information (PHI)
- Admission and informed consent documents
- Assessment of the home, if applicable
- Initial assessments
- Ongoing assessments, if applicable
- Notice of receipt of Client/Patient Rights and Responsibilities statement
- Notice of receipt of the Medicare DMEPOS Supplier Standards, if applicable

If the organization has electronic medical records (EMR), the organization has written policies and procedures and a mechanism to maintain all client/patient records in an electronic format. The EMR is in compliance with federal and state requirements.

*A physician or other licensed practitioner with prescribing authority

Evidence: Written Policies and Procedures
Evidence: Client/Patient Record

Services applicable: AIC, CLRM, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX5-1C: Written policies and procedures are established and implemented that address access, storage, removal, retention and destruction of client/patient records and information.

Written policies and procedures are consistent with Health Insurance Portability and Accountability Act (HIPAA) standards that include, but are not limited to:

- Who can have access to client/patient records
- Personnel authorized to enter information and review the records
- Any circumstances and the procedure to be followed to remove client/patient records from the premises or designated electronic storage areas
- A description of the protection and access of computerized records and information
- Back-up procedures, that include, but are not limited to:
    - Electronic transmission procedures
    - Storage of back-up disks and tapes
    - Methods to replace information, if necessary
- Conditions for release of information

All active client/patient records are kept in a secure location. Current electronic client/patient records are stored in an appropriate secure manner to maintain the integrity of the client/patient data through routine back-ups on-or off-site. Client/patient record information is safeguarded against loss or unauthorized use. An organization has written consent from the client/patient to release information not authorized by law.

All client/patient records are retained for a minimum of seven years from the date of the most recent discharge, the death of the client/patient, or per state law. Records of minor clients/patients are retained until at least seven years following the client's/patient's 18th birthday or according to state laws and regulations. The organization's policies and procedures provide retention requirements even if the organization discontinues operations.

The organization has specific written policies and procedures delineating how to destroy client/patient records. The destruction of client/patient records delegated to an outside commercial entity is covered by a written contract and Business Associates Agreement (BAA) to protect all Protected Health Information (PHI).

Portions of client/patient records may be copied and removed from the premises to ensure that appropriate personnel have information readily accessible to enable them to provide the appropriate level of care.

The organization has specific written policies and procedures delineating how these copies will be transported and stored to preserve confidentiality of information.

The client/patient record, whether in hard copy or electronic form, is made readily available on request by an appropriate authority.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX5-1D: Client/patient records contain documentation of all care/services provided. All entries are legible, clear, complete, and appropriately authenticated and dated in accordance with accepted standards of practice.

The client/patient record contains documentation of all care/service provided, directly or by contract, and has entries dated and signed by the appropriate personnel. Each home visit, treatment, or care/service is documented in the client/patient record and signed by the individual who provided the care/service. Signatures are legible, legal, and include the proper designation of any credentials.

Stamped physician* or clinical personnel signatures on orders, treatments, or other documents that are part of the client's/patient's record are not accepted.

*A physician or other licensed practitioner with prescribing authority

Evidence: Client/Patient Records
Evidence: Policy and Procedure

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX5-3A: Written policies and procedures are established that describe the process for evaluation/assessment and the plan of service.

Written policies and procedures describe the process for a client/patient evaluation/assessment and development of the plan of service. An appropriately trained individual conducts the initial evaluation/assessment to determine eligibility, care, and support needs of the client/patient. The plan of service should be appropriate for the type of care/service that is needed.

Evidence: Written Policies and Procedures

Services applicable: CRDS, Fitter, HME, MSP, RTS

Standard DRX5-3D: All clients/patients referred for Home Medical Equipment (HME) services have an evaluation/ assessment and plan of service completed.

There is an initial evaluation/assessment for each client/patient. The evaluation/assessment is used to determine the client's/ patient's problems, needs, and goals. The plan of service is developed during the initial evaluation/assessment conducted by an appropriately trained individual.

The evaluation/assessment includes, but is not limited to:

Client/patient information:
- Client/patient demographics

Physical health component:
- Prescription
- Anticipated length of need
- Physician* name and signature
- Type of supplies needed
- Diagnosis
- Special needs of client, if applicable

The environmental component:
- Identification of safety or health hazards
- Presence of adequate living arrangements

- Home environmental assessments including the potential for safety and security hazards (i.e., throw rugs, furniture layout, bathroom safety, cluttered stairways and blocked exits, unsecured doors, lack of smoke detectors, and fire risks)

The economic component:
- A review of the financial resources available to pay for the services/care provided

Functional limitations:
- Client's/patient's ability to use equipment/supplies provided and any limitations that may affect their ability to use the equipment

Social component:
- Identification of the responsible party
- An emergency contact
- Client/patient understanding of how to contact company in case of an emergency

An evaluation/assessment is performed and documented in the client's/patient's record. The evaluation/assessment focuses on appropriateness for care/service in the home, safety in the home, and care/services needed. The evaluation/assessment is used to determine if the equipment ordered meets the client/patient needs.

The initial plan of service includes, but is not limited to:
- Type and quantity of equipment/supplies needed
- Physician's* orders, if applicable
- Problems or additional client/patient needs

The plan of service can be combined with the evaluation/assessment on a single form as long as all components of the plan of service are included or the organization can use multiple documents to meet this requirement.

*A physician or other licensed practitioner with prescribing authority

Evidence: Client/Patient Records
Evidence: Observation

Services applicable: HME

Standard DRX5-4A: The organization shows evidence of the client/patient participation in the plan of care/service.

The client/patient has a right to be involved in the development of the plan of care/service and any changes in that plan. The degree of involvement may vary depending on the status of the client/patient. At a minimum, the client/patient agrees to the plan of care/service prior to the beginning of services and as subsequent changes occur.

Methods used to document the clients/patients participation include, but are not limited to:

- The plan of care/service may be signed by the client/patient
- A notation may be made in the client/patient record that the client/patient participated in the development of the plan of care/service

There may be documentation in the client/patient record that the plan of care/service was reviewed and accepted by the client/patient.

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX5-4D: There is evidence of changes to the plan of service for Home Medical Equipment (HME) and Complex Rehabilitation and Assistive Technology Supplier (RTS) services based on reassessment of client/patient needs.

There is a process in place to reassess the needs of the client/patient, based on changes in the client's/patient's condition. This reassessment must be done before the prescription expires and/or when there is a change in the equipment/supplies required.

The reassessment includes, but is not limited to:

- New supplies/equipment needed
- Change in client/patient condition
- Change in functional status of client/patient
- Change of environmental status

- Any other needs the client/patient requests

Client/patient agrees to continuation of service.

Evidence: Client/Patient Records

Services applicable: HME, RTS

Standard DRX5-5B: Written policies and procedures are established and implemented that describe the process for client/patient education.

Written policies and procedures describe client/patient education. The policies and procedures include, but are not limited to:

- Proper use of equipment provided
- Safety hazards associated with equipment provided
- Maintenance of equipment
- Plan of care/service
- How to notify the company of problems, concerns, and complaints
- Information/or instructions about infection control related to use of equipment

Written and verbal instructions are provided to the client/patient regarding the safe use and care of any equipment/supplies provided. Receipt of instructions must be documented in the client/patient record.

Evidence: Written Policies and Procedures
Evidence: Client/Patient Records
Evidence: Response to Interview

Services applicable: CLRM, Fitter, HME, RTS

Standard DRX5-5E: Client/patient and/or caregiver education focus on goal and outcome achievement as established in the plan of care.

Client/patient education is an integral part of services provided. Assessment of the client/patient knowledge deficits and learning abilities are evaluated during the initiation of care/services.

Client/patient education/instruction proceeds in accordance with the client's/patient's willingness and ability to learn.

The client/patient record must indicate education to the client/patient about appropriate actions to take if a medication or treatment reaction occurs when a healthcare professional is not present.

The client/patient record includes documentation of all teaching, client's/patient's response to teaching, and the client's/patient's level of progress/achievement of goals/outcomes.

Note: "Documentation provided to the client/patient" is defined as either providing written documentation or written instructions on how to find the information on the organization's website. If the client/patient does not have access to the website or requests a written copy, written documentation is provided to the client/patient, with proof of receipt documented in the client/patient record.

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, RTS, SRX, SRXONLY

Standard DRX5-8A: The organization does not supply services or products that are not specifically requested by a client/patient or the physician*/practitioner that has responsibility for the client/patient care.

Client/patient records contain documentation that any product provided was ordered by the physician* and requested by the client/patient/caregiver. For refill orders, there is documentation in the client/patient record of the items needed for refill, confirmation of the need for the refill, and who requested it.

*A physician or other licensed practitioner with prescribing authority

Evidence: Client/Patient Records

Services applicable: CRDS, CRTL, Fitter, HME, MSP, RTS

Standard DRX5-10A: Written policies and procedures are established and implemented in regard to the verification of credentials of the referring physician* or other licensed independent practitioners approved by law to prescribe medical services, treatments, and/or pharmaceuticals being conducted prior to providing care/service.

Written policies and procedures describe the process for verification of referring practitioner's credentials. Periodic assessments of the current physician's* and other licensed independent practitioner's credentials are obtained from the state and federal boards. The organization has a mechanism to ensure that orders are only accepted from currently credentialed practitioners.

This standard is applicable when an organization is required to have a physician's, nurse practitioner's and/or physician assistant's order to provide care/service.

*A physician or other licensed practitioner with prescribing authority

Evidence: Written Policies and Procedures
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX5-11A: Clients/patients are informed of expected time frames for delivery of equipment/supplies.

Clients/patients are notified when equipment/supplies will be delivered and/or shipped.

Evidence: Response to Interviews

Services applicable: CRCS, Fitter, HME, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX5-12A: Written policies and procedures are established and implemented for addressing client/patient needs that cannot be met by the organization. Clients/patients are referred to other agencies when appropriate. The prescribing physician* and/or referral source is notified within five days if the equipment or services ordered cannot be provided.

Care/service needs that cannot be met by the organization will be addressed by referring the client/patient to other organizations when appropriate.

The organization maintains a referral log or other tool to record when clients/patients are referred to another organization. Referral sources are notified when client's/patient's needs cannot be met and are not being accepted by the organization. The prescribing physician* and/or referral source is notified within five days if the equipment or services ordered cannot be provided.

Personnel are knowledgeable about other care/services available in the community.

*A physician or other licensed practitioner with prescribing authority

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX5-15D: Written policies and procedures are established and implemented that describe the process for transfer or discharge of a client/patient receiving services.

The discharge/transfer is noted in the client/patient record and includes:

- Date of discharge/transfer
- Reason for discharge/transfer
- Any instructions given to the client/patient

Evidence: Written Policies and Procedures
Evidence: Client/Patient Records

Services applicable: Fitter, HME, RTS

Section 6: QUALITY OUTCOMES/PERFORMANCE IMPROVEMENT

The standards in this section apply to the organization's plan and implementation of a Performance Improvement (PI) program. Items addressed in these standards include who is responsible for the program, activities being monitored, how data is compiled, and corrective measures being developed from the data and outcomes.

Standard DRX6-1A: The organization develops, implements, and maintains an effective, ongoing, organization-wide Performance Improvement (PI) program. The organization measures, analyzes, and tracks quality indicators that enable the organization to assess processes of care, services and operations. Organization-wide Performance Improvement (PI) efforts address priorities for improved quality of care/service, client/patient safety, and that all improvement actions are evaluated for effectiveness.

Each organization develops a program that is specific to its needs. The methods used by the organization for reviewing data include, but are not limited to:

- Current documentation (e.g., review of client/patient records, incident reports, complaints, and client/patient satisfaction surveys)
- Client/patient care/services
- Direct observation in the care/service setting
- Operating systems
- Interviews with clients/patients and/or personnel

The data collected by the organization for self-assessment includes, but is not limited to:

- Adverse events
- Client/patient complaints
- Client/patient records
- Satisfaction surveys
- Billing and coding errors for durable medical equipment, supplies, orthotic and prosthetic products, nutritional and parenteral nutrients.
- At least one important aspect related to care/service provided

Evidence: Written Policies and Procedures/PI Plan
Evidence: Observation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX6-1B: The organization ensures the implementation of an organization-wide Performance Improvement (PI) plan by the designation of a person responsible for coordinating PI activities.

Duties and responsibilities relative to PI coordination include:

- Assisting with the overall development and implementation of the PI Plan
- Assisting in the identification of goals and related client/patient outcomes
- Coordinating, participating in, and reporting activities and outcomes

The owner, manager, supervisor, or other designated personnel may be responsible for coordinating PI activities, and these duties are included in the individual's job description.

Evidence: Job Description

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-1C: There is evidence of personnel involvement in the Performance Improvement (PI) process.

Personnel receive training related to PI activities and their involvement. Training includes, but is not limited to:

- The purpose of PI activities
- Person responsible for coordinating PI activities
- Individual's role in PI
- PI outcomes resulting from previous activities

Personnel are involved in the evaluation process through carrying out PI activities, evaluating findings, recommending action plans, and/or receiving reports of findings.

Evidence: Observation
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-1D: There is an annual Performance Improvement (PI) report written.

There is a comprehensive, written annual report that describes the PI activities, findings, and corrective actions that relate to the care/service provided. In a large multi-service organization, the report may be part of a larger document addressing all of the organization's programs.

While the final report is a single document, improvement activities must be conducted at various times during the year. Data for the annual PI report may be obtained from a variety of sources and methods, (e.g., audit reports, client/patient questionnaires, feedback from referral sources, and outside survey reports).

Evidence: Performance Improvement Annual Report

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-2A: Each performance improvement (PI) activity or study contains the required items.

Each PI activity/study includes the following items:

- A description of indicator(s) to be monitored/activities to be conducted
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Methods of data collection
- Acceptable limits for findings or thresholds
- Who will receive the reports
- Written plan of correction when thresholds are not met
- Plans to re-evaluate if findings fail to meet acceptable limits
- Any other activities required under state or federal laws or regulations

The above criteria are used to develop each required PI activity.

Evidence: Performance Improvement Activities/Studies

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-3B: Performance Improvement (PI) activities include ongoing monitoring of at least one important aspect related to the care provided.

The organization conducts monitoring of at least one important aspect of the care/service provided by the organization. An important aspect of care/service reflects a dimension of activity that may be high-volume (occurs frequently or affects a large number of clients/patients), high-risk (causes a risk of serious consequences if the care/service is not provided correctly), or problem-prone (has tended to cause problems for personnel or clients/patients in the past).

Examples of activities include, but are not limited to:

- Delivery of care/service (e.g., timeliness and incorrect product deliveries)
- Medication administration
- Clinical procedures

Evidence: Performance Improvement Reports

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-3C: Performance Improvement (PI) activities include satisfaction surveys.

The PI Plan identifies the process for conducting client/patient satisfaction surveys.

The organization seeks input from personnel and referral sources as part of their performance improvement process to improve care/services.

Evidence: Performance Improvement Reports

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-3D: Performance Improvement (PI) activities include a review of the client/patient records.

The client/patient record review is conducted by all disciplines or members of the client/patient care/service team. An adequate sampling of open and closed records is selected to determine the completeness of documentation.

Evidence: Performance Improvement Reports

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-3E: Performance Improvement (PI) activities include the ongoing monitoring of client/patient grievances/ complaints.

PI activities include ongoing monitoring of client/patient complaints and the action(s) needed to resolve complaints and improve client/patient care/service.

Evidence: Performance Improvement Reports

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-3F: Written policies and procedures are established and implemented by the organization to identify, monitor, report, investigate, and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve client/patient care/service.

Written policies and procedures describe the process for identifying, reporting, monitoring, investigating, and documenting all adverse events, incidents, accidents, variances, or unusual occurrences. Policies and procedures include, but are not limited to:

- Action to notify the supervisor or after-hours personnel.
- Time frame for verbal and written notification.
- Appropriate documentation and routing of information.
- Guidelines for notifying the physician*, if applicable.
- Guidelines for notifying those affected when the event investigation indicates.
- Follow-up reporting to the administration/board/owner.

Written policies and procedures identify the person responsible for collecting incident data and monitoring trends, investigating all incidents, taking necessary follow-up actions, and completing appropriate documentation.

The organization investigates all adverse events, incidents, accidents, variances, or unusual occurrences that involve client/patient services and develops a plan of correction to prevent the same or similar event from occurring again. Events include, but are not limited to:

- Unexpected death.
- A serious injury.
- Significant adverse drug reaction, if applicable.
- Significant medication error, if applicable.
- Other undesirable outcomes as defined by the organization.
- Adverse client/patient care outcomes.
- Client/patient injury (witnessed and unwitnessed) including falls that are related to equipment and/or supplies provided.
- Equipment failure.

Written policies and procedures address the organization’s compliance with the Food and Drug Administration (FDA) Medical Device Tracking program and facilitation of any recall notices submitted by the manufacturer, if applicable.

There is a standardized form developed by the organization used to report incidents. The organization documents all incidents, accidents, variances, and unusual occurrences. The investigation is initiated within 24 hours after an organization becomes aware of an incident resulting in a client’s/patient’s hospitalization or death. For other occurrences, the organization investigates within 72 hours after being made aware of the incident, accident, variances, or unusual occurrences.

This data is included in the PI Plan. The organization assesses and utilizes the data for reducing further safety risks.

*A physician or other licensed practitioner with prescribing authority

Evidence: Written Policies and Procedures
Evidence: Incident/Variance Reports
Evidence: Performance Improvement Reports

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-3G: Performance Improvement (PI) activities include ongoing monitoring of billing and coding errors.

The organization tracks the number of billing inconsistencies found through client/patient record reviews as well as errors found through Medicare and third-party payor claim denials.

Evidence: Performance Improvement Reports

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-3I: The organization monitors all care/service provided under contract/agreement to ensure that care/services are delivered in accordance with the terms of the contract/agreement.

The organization has implemented a process for monitoring all care/service provided under a contract/agreement. Processes include, but are not limited to:

- Satisfaction surveys
- Record reviews
- On-site observations and visits
- Client/patient comments and other performance improvement activities

Data and outcomes from monitoring activities are reported to the organization's leadership to ensure the overall quality of the care provided to the client/patient.

Evidence: Performance Improvement Activates
Evidence: Governing Body Meeting Minutes or Leadership Meeting Documentation

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX6-6A: There is evidence of involvement of the governing body/owner.

The governing body/owner and leaders are ultimately responsible for all actions and activities of the organization; therefore, their role in the evaluation process and the responsibilities delegated to personnel must be clearly documented.

There is evidence that the results of Performance Improvement (PI) activities are communicated to the governing body/owner and organizational leaders.

The organization's leaders allocate resources for implementation of the PI Program.

Resources include, but are not limited to:

- Training and education programs regarding PI
- Personnel time
- Information management systems

Evidence: Board of Director Meeting Minutes

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Section 7: RISK MANAGEMENT: INFECTION AND SAFETY CONTROL

The standards in this section apply to the surveillance, identification, prevention, control, and investigation of infections and safety risks. The standards also address environmental issues, such as fire safety, hazardous materials, and disaster and crisis preparation.

Standard DRX7-1A: Written policies and procedures are established and implemented that address the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases and the compliance with regulatory standards.

The organization maintains and documents an effective infection control program that protects clients/patients and personnel by preventing and controlling infections and communicable diseases.

The organization's infection control program identifies risks for the acquisition and transmission of infectious agents in all care/service settings. There is a system to communicate with all personnel and clients/patients about infection prevention and control issues, including their role in preventing the spread of infections and communicable diseases through daily activities.

Written policies and procedures are established and implemented that include accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

Accepted standards of practice for healthcare providers are typically developed by government agencies, professional organizations and associations. Examples include, but are not limited to:

- The Centers for Disease Control and Prevention (CDC)
- The Agency for Healthcare Research and Quality (AHRQ)
- State Practice Acts
- Commonly accepted health standards established by national organizations, boards, and councils (e.g., Association for Professionals in Infection Control and Epidemiology [APIC]; and American Nurses Association [ANA])

Written policies and procedures include, but are not limited to:

- General infection control measures appropriate for care/service provided
- Hand-washing
- Use of standard precautions and personal protective equipment (PPE)
- Needle-stick prevention and sharps safety, if applicable
- Appropriate cleaning/disinfecting procedures
- Infection surveillance, monitoring, and reporting of employees and clients/patients (client/patient monitoring is not applicable to Mail-Order Pharmacy services)

- Disposal and transportation of regulated waste, if applicable
- Precautions to protect immune-compromised clients/patients
- Employee health conditions limiting their activities
- Assessment and utilization of data obtained about infections and the infection control program

The organization conducts an annual tuberculosis (TB) risk assessment (an Occupational Safety and Health Administration (OSHA) requirement). Written policies and procedures detail OSHA Blood Borne Pathogen and TB Exposure Control Plan training for all direct care personnel. The exposure control plans are reviewed annually and updated to reflect significant modifications in tasks or procedures that may result in occupational exposure. The TB Exposure Control Plan includes engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent (e.g., use of safer medical devices and appropriate respiratory protection devices). Plans are available to personnel at the workplace during the work shift.

The annual TB risk assessment is also used to determine the need, type, and frequency of testing/assessments for direct care personnel. (refer to standard DRX4-2C for TB testing and symptom assessment.)

The organization assigns individual(s) who are responsible for implementing the infection control activities and personnel education.

The organization provides infection control education to employees, and contracted providers regarding both basic and high-risk infection control procedures as appropriate to the care/services provided. Clients/patients are educated on infection control procedures as related to the product and/or service they receive.

All personnel demonstrate infection control procedures in the process of providing care/service to clients/patients as described in OSHA and CDC standards and as adopted into program care/service policies and procedures.

Evidence: Written Policies and Procedures
Evidence: Observation

Evidence: Response to Interviews
Evidence: Client/Patient Records

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX7-2A: Written policies and procedures are established and implemented that address the education of personnel concerning safety.

Written policies and procedures include types of safety training as well as the frequency of training. Safety training is conducted during orientation and at least annually for all personnel.

Safety training activities include, but are not limited to:

- Body mechanics
- Safety management:
    - Fire
    - Evacuation
    - Security
    - Office equipment
    - Environmental hazards
- Personnel safety techniques

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX7-2B: Written policies and procedures are established and implemented that address client/patient safety in the home.

Written policies and procedures are established and implemented that address client/patient safety in the home. The safety training activities include, but are not limited to:

- Compliance monitoring measures relating to the client's/patient's medication, if applicable
- Safety measures relating to oxygen use, if applicable
- Client/patient medical equipment safety, if applicable
- Basic home safety measures (e.g., household chemicals, throw rugs, furniture layout, cluttered stairways, blocked exits, bathroom safety, and electrical safety)

Personnel receive training on home safety during orientation and at least once annually.

Evidence: Written Policies and Procedures
Evidence: Response to Interviews

Services applicable: CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS

Standard DRX7-4A: Written policies and procedures are established and implemented that outline the process for meeting client/patient needs in a disaster or crisis situation.

Written policies and procedures describe a process to organize and mobilize personnel adequate to secure resources needed to meet client/patient needs in the event of a disaster or crisis. The process includes:

- A system to identify alternative methods for contacting personnel
- Mobilizing resources to meet critical needs
- Alternative methods, resources, and travel options for the provision of care/service
- Safety of personnel
- Identified time frames for initiation of the plan
- Specific measures for anticipated emergencies typical or appropriate for the geographical area served (e.g., hurricanes, tornadoes, floods, earthquakes, chemical spills, and inclement weather)
- A system to identify and prioritize clients/patients based upon their need so that care/service is ensured for clients/patients whose health and safety might be at risk

The organization has, at a minimum, an annual practice drill to evaluate the adequacy of its plan.

The emergency plan also describes access to "911" Emergency Medical Services (EMS) in the event of needed emergency care/

services for clients/patients and personnel.

The organization educates all personnel about the process to meet client/patient needs in a disaster or crisis situation.

This standard does not apply to Community Retail or Medical Supply providers who do not supply rental equipment or equipment/supplies that require the client/patient to have a backup plan in place if equipment fails to operate or supplies run out.

The following are examples of when this standard would apply to Community Retail and Medical Supply providers:

- Enteral pumps are rented to clients/patients who are dependent on the pump for their daily food intake and would need access to supplies to provide nutrition through a manual method of delivery
- An organization has clients/patients who are dependent on urological or ostomy products and must have a backup plan in place if they run out of products.

Evidence: Written Policies and Procedures
Evidence: Disaster Drill Log
Evidence: Observation
Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX7-4C: The organization provides education to client/patient/caregiver regarding emergency preparedness.

This education includes information regarding:

- How to contact the organization
- How to handle the equipment, if applicable
- How to handle a missed treatment or delivery

Note: "Documentation provided to the client/patient" is defined as either providing written documentation or written instructions on how to find the information on the organization's website. If the client/patient does not have access to the website or requests a written copy, written documentation is provided to the client/patient, with proof of receipt documented in the client/patient record.

Evidence: Client/Patient Education Material
Evidence: Client/Patient Records

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MSP, RTS, SRX, SRXONLY

Standard DRX7-5B: Written policies and procedures are established and implemented that address the organization's fire safety and emergency power systems.

Written policies and procedures or a fire safety plan address fire safety and management for all office and worksite environments.
The written policies and procedures include, but are not limited to:

- Providing emergency power to critical areas, such as:
    - Alarm systems, if applicable
    - Illumination of exit routes
    - Emergency communication systems
- Testing of emergency power systems (at least annually)
- A no-smoking policy and how it will be communicated
- Maintenance of:
    - Smoke detectors
    - Fire alarms
    - Fire extinguishers
- Fire drills:
    - Conducted at least annually
    - Evaluated and results communicated to all personnel

Personnel are trained on the fire safety plan and emergency power systems.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX7-6A: Written policies and procedures are established and implemented for the acceptance, transportation, pickup, and/or disposal of hazardous chemicals and/or contaminated materials used in the provision of client/patient care/service.

Written policies and procedures include safe methods of handling, labeling, storage, transportation, disposal, and pickup of hazardous wastes, hazardous chemicals, and/or contaminated materials used in the home/organization. The organization follows local, state, and federal guidelines.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Patient Records

Services applicable: AIC, CRCS, HME, IRN, IRX, IRX-NO797, MORX, RTS, SRX, SRXONLY

Standard DRX7-6B: Written policies and procedures are established and implemented for following Occupational Safety and Health Administration's (OSHA's) Hazard Communication Standard that describes appropriate labeling of hazardous chemicals and/or materials, instructions for use, and storage and disposal requirements.

Written policies and procedures and their implementation follow OSHA's Hazard Communication Standard, detailing:

- The labeling of containers of hazardous chemicals and/or materials with the identity of the material and the appropriate hazard warnings
- Current Safety Data Sheets (SDS) must be accessible to personnel
- The proper use, storage, and disposal of hazardous chemicals and/or materials
- The use of appropriate personal protective equipment (PPE)

Written policies and procedures address how personnel handle an exposure to a hazardous product while in the home environment. (Does not apply to Mail-Order Pharmacy services.)

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: AIC, CRCS, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX7-10B: Nutritional products are stored in accordance with the manufacturer's guidelines.

The organization ensures that enteral products are stored correctly at the organization and the client's/patient's home. Enteral products are properly labeled according to organizational manufacturer's guidelines.

The organization tracks product lot numbers in case of manufacturer recall.

Enteral products are stored in a climate-controlled environment as outlined by the manufacturer. Clients/patients are instructed on proper storage of nutritional therapy products in their home.

Expired products are disposed of per manufacturer's guidelines.

Evidence: Client/Patient Records
Evidence: Observation

Services applicable: CRDS, CRTL, HME, IRX, IRX-NO797, MORX, MSP, SRX, SRXONLY

Standard DRX7-11A: Written policies and procedures are established and implemented for identifying, monitoring, reporting, investigating, and documenting all incidents, accidents, variances, or unusual occurrences involving personnel.

Written policies and procedures describe the process for reporting, monitoring, investigating, and documenting a variance. Policies and procedures include, but are not limited to:

- Action to notify the supervisor or after-hours personnel
- Time frame for verbal and written notification
- Appropriate documentation and routing of information
- Guidelines for medical care
- Follow-up reporting to the administration/board/owner

Written policies and procedures address compliance with OSHA guidelines regarding the recording of work-related injuries and illnesses that are diagnosed by a physician* or licensed healthcare professional and any work-related injuries and illnesses that meet any of the specific recording criteria listed in 29 CFR 1904.8 through 1904.11, as applicable to the organization.

Written policies and procedures identify the person responsible for collecting incident data and monitoring trends, investigating all incidents, taking necessary follow-up actions, and completing appropriate documentation.

Incidents to be reported include, but are not limited to:

- Personnel injury or endangerment
- Motor vehicle accidents when conducting agency business
- Environmental safety hazards
- Equipment safety hazards, malfunctions, or failures
- Unusual occurrences

There is a standardized form developed by the organization used to report incidents. The organization documents all incidents, accidents, variances, and unusual occurrences. The investigation is initiated within 24 hours after an organization becomes aware of an incident resulting in an employee's hospitalization or death. The organization investigates other occurrences within 72 hours after being made aware of the incident, accident, variances, or unusual occurrences.

The reports are distributed to management and the governing body/owner and are reported as required by applicable laws and regulations. This data is included in the PI Program. The organization assesses and utilizes the data for reducing further safety risks.

The organization educates all personnel on its policies and procedures for documenting and reporting incidents/variances.

*A physician or other licensed practitioner with prescribing authority

Evidence: Written Policies and Procedures
Evidence: Incident Reports
Evidence: Response to Interviews
Evidence: OSHA 300, 300A and 301 Forms, if applicable
Evidence: PI reports

Services applicable: AIC, CRCS, CRDS, CRTL, Fitter, HME, IRN, IRX, IRX-NO797, MORX, MSP, RTS, SRX, SRXONLY

Standard DRX7-12C: Written policies and procedures are established for the provision of products and equipment for Home Medical Equipment (HME) and Complex Rehabilitation and Assistive Technology (RTS) services.

The written policies and procedures include, but are not limited to:

- Storage, and transportation of client/patient-ready equipment/supplies
- Separation of dirty, inoperable, and clean equipment in warehouse and delivery vehicle
- Equipment being returned to the organization for processing:
- Use of cleaning and disinfecting agents and processing of contaminated or soiled equipment
    - Function testing
- Warehousing and segregation of equipment
- Environmental assessments, setup, electrical safety, and demonstration of safe and proper use of all home medica equipment (HME), complex rehabilitation and assistive technology supplier (RTS) equipment according to manufacturer’s guidelines
- Routine maintenance, preventative maintenance, and repairs are performed according to manufacturer’s guidelines and documented
- Separation and removal/disposal of expired products including the requirement of a quarantine area
- Calibration per manufacturer’s guidelines, if applicable
- Inspection and storage of oxygen tanks, if applicable
- Separation of full and empty oxygen tanks, if applicable
- Tracking of products with lot and/or serial numbers:
    - Equipment
    - Compressed gas
    - Nutritional products
    - Other products
- Rotation of stock
- Verification that products are not counterfeit, altered, misbranded or mislabeled prior to distribution to the client/patient

Written policies and procedures define requirements to be met for personnel who perform routine maintenance and repair of all equipment, which include the following:

- Training

- Qualifications
- Skill validation

The written policies and procedures for product recalls address:

- Removal of inventory from current inventory
- Notification of all clients/patients having recalled items
- The immediate removal of recalled equipment or supplies from client-/patient-ready inventory
- The exchange of recalled equipment/supplies in the field

There are written policies and procedures for tracking product lot numbers as required for possible recalls by the FDA and/or manufacturer. If there are certain items that are only general supplies such as nasal cannulas, oxygen tubing, or lancets that have lot numbers but are not routinely tracked, then there needs to be a system in place and outlined in the policies and procedures on how a recall of these products would be followed to ensure the safety of the client/patient.

Evidence: Written Policies and Procedures

Services applicable: CRCS, HME, RTS

Standard DRX7-12D: Personnel implement the organization's policies and procedures for the cleaning, storage, safe transportation, delivery, and setup of equipment used in the provision of care/service. Implementation includes a home environmental and electrical safety assessment.

The organization practices their policies and procedures for:

- Storage, and transportation of client-/patient-ready equipment/supplies
- Separation of dirty, inoperable, and clean equipment in warehouse and delivery vehicle
- Equipment being returned to the organization for processing
  - Use of cleaning and disinfecting agents and processing of contaminated or soiled equipment
  - Function testing

- Warehousing and segregation of equipment
- Environmental assessments, setup, and demonstration of safe and proper use of all Home Medical Equipment (HME)/ Complex Rehabilitation and Assistive Technology Supplier (RTS) equipment according to manufacturer's guidelines
- Separation and removal/disposal of expired products including the requirement of a quarantine area
- Tracking of products with lot and/or serial numbers, and manufacturer’s recalls
  - Equipment
  - Compressed gas
  - Nutritional products
  - Other products
- Rotation of stock
- Inspection and storage of oxygen tanks, if applicable
- Separation of full and empty oxygen tanks, if applicable
- Calibration per manufacturer’s guidelines, if applicable
- Routine maintenance, preventative maintenance, and repairs are performed according to manufacturer's guidelines and documented
- Verification that products are not counterfeit, altered, misbranded, or mislabeled prior to distribution to the client/patient.
- Personnel who perform routine maintenance and repair of all equipment have documented training and skill validation

The organization practices safe procedures in the delivery of equipment:

- Vehicle has a method to secure equipment for safe transportation
- Vehicle has secure oxygen tanks racks, if applicable
- Vehicle is neat and clean
- Oxygen manifest is available, if applicable
- Vehicle has a method to separate clean and dirty equipment
- Safety Data Sheets (SDSs) are accessible/available, if applicable
- Vehicles used for delivery of product comply with all applicable laws and regulations

At time of delivery, electrical safety is evaluated that includes, but is not limited to:

- Safety and adequacy of electrical outlets
- Safe use of extension cords and outlet adapters
- Location and function of all equipment controls and equipment circuit breakers

There is inventory or the ability to order inventory that the organization is accredited or asking to be accredited for.

Evidence: Observation
Evidence: Response to Interviews

Evidence: Personnel Files

Services applicable: CRCS, HME, RTS

Standard DRX7-12E: Personnel implement the organization's policies and procedures relating to back-up equipment/plan for use during power failures or malfunctions in the client/patient home.

Client/patient home medical equipment backup systems comply with the organization's policies and procedures and applicable state laws.

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: CRCS, HME, IRN, IRX, IRX-NO797, RTS, SRX

Standard DRX7-13A: Written policies and procedures are established and implemented for organizations that transfill oxygen.

Written policies and procedures are established and implemented for organizations that transfill oxygen (gas and/or liquid) which include, but are not limited to:

- FDA transfilling requirements
- Label inventory
- Transfilling logs
- Calibration and filter changes of analyzers
- Annual training documentation
- Annual maintenance of filing system to include certification of gauges, thermometers, etc.
- Current FDA registration and manufacturer license/permit as required by state law
- Oxygen complaint logs

Companies providing oxygen comply with FDA guidelines for quarantine of expired product, cylinder static testing expiration, and quarantine of oxygen receiving consumer complaints.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews
Evidence: Personnel Files

Services applicable: HME

Standard DRX7-16A: A warranty is provided on all applicable products.

The organization provides a warranty to each client/patient that includes the following:

- A product warranty is given to the client/patient on all applicable products
- The warranty may be the one offered by the product manufacturer, the provider, or a combination of both
- Items that are custom-fabricated are covered by a written warranty
- The client/patient is made aware of the specifics of the warranty including the duration, what is covered, owner responsibilities for maintenance/care, and expenses involved in repair/replacement such as labor, shipping, or delivery
- The client/patient is made aware of the actions that may void a warranty, particularly if the product needs to be modified for any reason

The organization develops and maintains a system for tracking warranty repairs and uses the collected information to assist clients/patients in making informed decisions about the products recommended.

Note: "Documentation provided to the client/patient" is defined as either providing written documentation or written instructions on how to find the information on the organization's website. If the client/patient does not have access to the website or requests a written copy, written documentation is provided to the client/patient, with proof of receipt documented in the client/patient record.

Evidence: Client/Patient Records
Evidence: Response to Interviews
Evidence: Observation

Services applicable: CLRM, CRDS, CRTL, Fitter, HME, IRX, IRX-NO797, MSP, RTS

Appendix A: Reference Guide for Required Documents, Policies and Procedures
Customized for: HME

Standard #	Documents, Policies and Procedures	Agency Notes
DRX1-3A	Written Policies and Procedures	
DRX2-1A	Written Policies and Procedures	
DRX2-2A	Written Policies and Procedures	
DRX2-3A	Written Policies and Procedures	
DRX2-4A	Written Policies and Procedures	
DRX2-5A	Written Policies and Procedures	
DRX2-7A	Written Policies and Procedures	
DRX2-8A	Written Policies and Procedures	
DRX2-8B	Written Policies and Procedures	
DRX2-9A	Written Policies and Procedures	
DRX4-1A	Written Policies and Procedures	
DRX4-2C	Written Policies and Procedures	
DRX4-2D	Written Policies and Procedures	
DRX4-2H	Written Policies and Procedures	
DRX4-2I	Written Policies and Procedures and/or Employee Handbook	
DRX4-2J	Written Policies and Procedures	
DRX4-6A	Written Policies and Procedures	
DRX4-7A	Written Policies and Procedures	
DRX4-8A	Written Policies and Procedures	
DRX4-11C	Written Contracts/Agreements	
DRX5-1A	Written Policies and Procedures	
DRX5-1C	Written Policies and Procedures	
DRX5-3A	Written Policies and Procedures	
DRX5-5B	Written Policies and Procedures	
DRX5-10A	Written Policies and Procedures	
DRX5-12A	Written Policies and Procedures	
DRX5-15D	Written Policies and Procedures	
DRX6-1A	Written Policies and Procedures/PI Plan	
DRX6-3F	Written Policies and Procedures	
DRX7-1A	Written Policies and Procedures	
DRX7-2A	Written Policies and Procedures	
DRX7-2B	Written Policies and Procedures	
DRX7-4A	Written Policies and Procedures	
DRX7-5B	Written Policies and Procedures	
DRX7-6A	Written Policies and Procedures	
DRX7-6B	Written Policies and Procedures	
DRX7-11A	Written Policies and Procedures	
DRX7-12C	Written Policies and Procedures	
DRX7-13A	Written Policies and Procedures	