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Aspen State Regulation Set: O 3.02 Home Medical Equipment

ST - O0000 - Initial Observations

Title Initial Observations

Statute or Rule

Type Memo Tag

Regulation Definition

Interpretive Guideline

These guidelines are meant solely to provide guidance to surveyors in the survey process.

ST - O0001 - Licensure

Title Licensure

Statute or Rule 400.93;(1-4) FS; 59A-002(1) FAC

Type Rule

Regulation Definition

Interpretive Guideline

400.93, F.S.

(1) Any person or entity that holds itself out to the public as providing home medical equipment and services or accepts physician orders for home medical equipment and services is subject to licensure under this part.

(2) Any person or entity that holds itself out to the public as providing home medical equipment that typically requires home medical services is subject to licensure under this part.

(3) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and to entities licensed by or applying for such licensure from the agency pursuant to this part. A license issued by the agency is required in order to provide home medical equipment and services in this state.

(4) A separate license is required of all home medical equipment providers operating on separate premises, even if the providers are operated under the same management.

Some providers are exempt from HME licensure as referenced in 400.93(5), which is pasted below, if they hold another state license and run their home medical equipment business from that same licensed location. However some providers, that own a HHA for example, may operate a HME under the same corporation management; have a different business name for the HME business and choose to obtain a separate HME license because they want to operate the HME business as a separate entity.

400.93(5), F.S., The following are exempt from home medical equipment provider licensure, unless they have a separate company, corporation, or division that is in the business of providing home medical equipment and services for sale or rent to consumers at their regular or temporary place of residence pursuant to the provisions of this part:

(a) Providers operated by the Department of Health or Federal Government.

(b) Nursing homes licensed under part II.

(c) Assisted living facilities licensed under chapter 429, when serving their residents.

(d) Home health agencies licensed under part III.

(e) Hospices licensed under part IV.

(f) Intermediate care facilities, homes for special services, and transitional living facilities licensed under part V.

(g) Hospitals and ambulatory surgical centers licensed under chapter 395.

(h) Manufacturers and wholesale distributors when not selling directly to consumers.

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59A-25.002(1), Florida Administrative Code (F.A.C.)

Home medical equipment locations requiring a license are any locations that sell, rent, or distribute, or offer to sell or rent to or for a consumer any home medical equipment that requires services. These locations can be identified as follows:

- (a) Any location providing or distributing home medical equipment requiring services to consumers in Florida;
- (b) Any location where an intake person takes calls from consumers in Florida and offers to sell or rent home medical equipment requiring services;
- (c) Any location where a consumer in Florida may call in response to a provider advertising to sell or rent home medical equipment requiring services,; e.g., television advertisements, toll-free telephone numbers, phone books, newspapers, flyers or any other forms of public advertisement;
- (d) Any location out of state that offers to sell or rent home medical equipment requiring services to consumers in Florida;
- (e) Any location in state or out of state, with sales representatives working in Florida, that offers to sell or rent home medical equipment requiring services to consumers in Florida, i.e., the sales representatives themselves do not need to be licensed; and
- (f) Any buildings, that are not located at the licensed central service center address, called shops, warehouses, distribution centers, or called by any other name, are required to have a license if that site location provides selection (via telephone, showroom or sales representative), delivery, set up, consumer instruction or maintenance of equipment to consumers in Florida.

1. A central service centers must provide the names and locations of all of its designated distribution centers on the licensure application.

2. A distribution centers must submit a separate licensure application and must specify the name of its central service

(i) Licensed health care practitioners who utilize home medical equipment in the course of their practice, but do not sell or rent home medical equipment to their patients.

(j) Pharmacies licensed under chapter 465.

59A-25.002(2), F.S., Home medical equipment locations that do not require a license: Diabetic monitors and disposable supplies, e.g., diabetic, ostomy, urological and wound care supplies have been identified as equipment and supplies that do not require services as defined in Section 400.925(9), F.S.; therefore, locations that supply these items only will not require a HME license.

See below for probes that may be used to determine if the person or entity is holding itself out to the public as selling or renting home medical equipment to consumers in Florida.

What is the purpose of this business location?

Does this location distribute home medical equipment to the surrounding community if based in Florida or near the Florida state line?

Does this location take calls from Florida consumers and offer to sell or rent home medical equipment?

Does this location advertise to sell or rent home medical equipment requiring services to Florida consumers from this location? Refer to the definition of home medical equipment above, the definition of ' life-supporting or life-sustaining equipment ' at 400.925(10), F.S. and 59A-25.003(2), F.A.C., for examples of home medical equipment.

Does this location provide selection, (via telephone, showroom, storefront or sales representative), delivery, set up, consumer instruction and/or maintenance to Florida consumers?

Do any brochures, stationery, insurance documents, accrediting documents, etc. list other locations that may need a license?

Note: If the surveyor has questions as to whether a business should be licensed, call the Home Care Unit and discuss with HME staff.

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center on the application.

3. Each licensed distribution center is required to meet all standards for licensure but may be determined to meet the standards through the activities of its designated central service center as referenced in paragraph 59A-25.005(1)(b), F.A.C.

ST - O0002 - Definitions

Title Definitions

Statute or Rule 400.925 FS; 59A-25.001 FAC

Type Memo Tag

Regulation Definition

Interpretive Guideline

400.925 Definitions.-As used in this part, the term:

- (1) " Accrediting organization " means an organization whose standards incorporate licensure regulations required by this state.
- (2) " Agency " means the Agency for Health Care Administration.
- (3) " Consumer " or " patient " means any person who uses home medical equipment in his or her place of residence.
- (4) " Department " means the Department of Children and Families.
- (5) " General manager " means the individual who has the general administrative charge of the premises of a licensed home medical equipment provider.
- (6) " Home medical equipment " includes any product as defined by the Federal Drug Administration ' s Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes oxygen and related respiratory equipment; manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or

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any splints, braces, or aids custom fabricated by a licensed health care practitioner; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need.

(7) " Home medical equipment provider " means any person or entity that sells or rents or offers to sell or rent to or for a consumer:

(a) Any home medical equipment and services; or

(b) Home medical equipment that requires any home medical equipment services.

(8) " Home medical equipment provider personnel " means persons who are employed by or under contract with a home medical equipment provider.

(9) " Home medical equipment services " means equipment management and consumer instruction, including selection, delivery, setup, and maintenance of equipment, and other related services for the use of home medical equipment in the consumer ' s regular or temporary place of residence.

(10) " Life-supporting or life-sustaining equipment " means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Life-supporting or life-sustaining equipment includes apnea monitors, enteral feeding pumps, infusion pumps, portable home dialysis equipment, and ventilator equipment and supplies for all related equipment, including oxygen equipment and related respiratory equipment.

(11) " Moratorium " means a mandated temporary cessation or suspension of the sale, rental, or offering of equipment after the imposition of the moratorium, in accordance with part II of chapter 408. Services related to equipment sold or rented prior to the moratorium must be continued without interruption, unless determined otherwise by the agency.

(12) " Premises " means those buildings and equipment which are located at the address of the licensed home medical

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equipment provider for the provision of home medical equipment services, which are in such reasonable proximity as to appear to the public to be a single provider location, and which comply with zoning ordinances.

(13) "Residence " means the consumer ' s home or place of residence, which may include nursing homes, assisted living facilities, transitional living facilities, adult family-care homes, or other congregate residential facilities.

59A-25.001 Definitions.

In addition to definitions contained in Chapter 400, Part VII and Chapter 408, Part II, F.S., the following terms shall apply to this rule chapter:

- (1) " AHCA " means Agency for Health Care Administration.
- (2) " Central Service Center " means the licensed premises that are in charge of taking consumer orders, dispatching the orders to licensed distribution centers owned and operated by the same licensee that provide home medical equipment services, and maintaining consumer and personnel records. The central service center is responsible for the operation of its designated distribution centers.
- (3) "Distribution centers" means those licensed premises that are not located at the address of the central service center but are owned and operated by the same licensee, receive orders from the central service center and are utilized to provide home medical equipment services.
- (4) HME means home medical equipment.

ST - O0004 - Change of General Manager

Title Change of General Manager

Statute or Rule 400.931(4)

Type Rule

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Regulation Definition

When a change of the general manager of a home medical equipment provider occurs, the licensee must notify the agency of the change within 45 days.

Interpretive Guideline

Verify that the general manager at the location is the same as the person listed on the most recent application or that the provider has notified the Home Care Unit of the change.

Note: If the general manager has changed since the last notification to the Home Care Unit, the surveyor must inform the Home Care Unit as soon as possible. The Home Care Unit will require the provider to attest to the new general manager's qualifications and provide proof of level 2-background screening. Refer to Tag O-0023 for qualifications of general manager.

CROSS REFERENCE tag O-0062 Emergency management plan - ANNUAL UPDATE

ST - O0005 - Insurance

Title Insurance

Statute or Rule 400.931(3); 408.810(7); 59A-25.002(5)

Type Rule

Regulation Definition

400.931(3), F.S.
As specified in part II of chapter 408, the home medical equipment provider must also obtain and maintain professional and commercial liability insurance. Proof of liability insurance, as defined in s. 624.605, must be submitted with the application. The agency shall set the required amounts of liability insurance by rule, but the required amount must not be less than \$250,000 per claim. In the case of contracted services, it is required that the contractor have liability insurance not less than \$250,000 per claim.

408.810(7), F.S.
If proof of insurance is required by the authorizing statute, that insurance must be in compliance with chapter 624, chapter 626, chapter 627, or chapter 628 and with agency rules.

Interpretive Guideline

Ask for a copy of the provider's insurance policy.

Make sure both professional and commercial coverage has been obtained and that the coverage is current.

Check to see that the address of the licensed location is listed on the policy or is listed as an addendum to the policy showing their multiple locations. (Professional liability is liability exposure due to procedures or services, such as consumer instruction and management. Commercial is liability due to bodily injury caused by product failure.)

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59A-25.002(5), F.A.C.

... A corporation can provide a blanket policy, which indicates that each of its licensed locations is insured under one policy, verifying not less than \$250,000 per claim for each location.

ST - O0007 - Contracts

Title Contracts

Statute or Rule 400.931(1)(c) FS; 59A-25.003(5)

Type Rule

Regulation Definition

400.931, F.S.

(1)(c) A listing of those with whom the applicant contracts, both the providers the applicant uses to provide equipment or services to its consumers and the providers for whom the applicant provides services or equipment.

59A-25.003(5), F.A.C.

Contracts: Services provided by contract for consumers must be through a written agreement between the provider and the business providing any equipment and services for a consumer, herein referred to as the contractor. Contracts must be retained for a minimum of 5 years. The contract must include the following at a minimum:

- (a) A description of any of the equipment or services to be provided by the contractor;
- (b) Designation if the HME provider or the contractor is responsible for monitoring the equipment and services provided by the contractor;
- (c) Charges for any contracted equipment and services and designation of who will be billing the consumer, the HME provider or the contractor;
- (d) Responsibility of the HME provider to retain and maintain all records of consumers served by a contractor;

Interpretive Guideline

-Determine if the provider is in a contractual relationship with any other persons or entities, either as a supplier or recipient of equipment and/or services. If so,

-Review each contract for language regarding the specific equipment and or services being provided such as type of equipment and type of services (delivery, setup, consumer education, clinical staff, etc.); and

-Check to see if the contract includes the requirements listed in 59A-25.003(5), F.A.C.; and Ask what is expected of the contractor with specific regard to services provided.

cross reference tag O-0005 Insurance

Note: A HME provider sells or rents directly to a consumer; a true contractor would not bill a consumer. Equipment provided and/or services rendered by a contractor would be reimbursed by the HME provider and then HME provider bill the consumer.

If a HME provider claims to have a contract and the contractor is selling or renting equipment directly to a consumer; then the person or entity referred to as the ' contractor ' needs a separate HME license. If the person or entity does not possess a HME provider license, then a referral for unlicensed activity must be made.

CROSS REFERENCE TAG O-0001 LICENSE AND O-Z827 UNLICENSED ACTIVITY

A contract is not required when a business does maintenance or repair only directly for a licensed HME provider . For example, a maintenance company that maintains equipment at its place of business and then returns the equipment to the HME provider rather than directly to the consumer.

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- (e) Evidence that the contractor has professional and commercial liability insurance coverage (the licensee is responsible for making sure that the contractor has liability insurance);
- (f) Period of the contract between the HME provider and the contractor;
- (g) Procedures for reporting service and maintenance notes and any clinical or progress notes by the contractor to the HME provider;
- (h) Date and signatures of all parties; and
- (i) Contracts must be retained for a minimum of five years.

Note: Providers that supply dialysis equipment to patients that receive home dialysis have an agreement with an End Stage Renal Disease (ESRD) back-up facility (the agreement is not technically called a contract but is referred to as a negotiated agreement). The important point is that all HME providers of home dialysis equipment must have an agreement with an ESRD that is serving as a backup to the patients receiving home dialysis treatment. The ESRD is responsible for monitoring the work of the HME provider and the health outcome of the patient. See tag O-00015 for more probes regarding equipment service for home dialysis equipment. The surveyor must verify an agreement is in place between the HME provider and the ESRD facility.

ST - O0008 - Inventory

Title Inventory

Statute or Rule 400.934(2); 400.931(1)(a); 59A-25.005(1)

Type Rule

Regulation Definition

400.934, F.S.

As a requirement of licensure, home medical equipment providers shall:

(2) Provide at least one category of equipment directly, filling orders from its own inventory.

400.931(1)(a), F.S.

... Categories of equipment include:

1. Respiratory modalities.
2. Ambulation aids.
3. Mobility aids.
4. Sickroom setup.
5. Disposables.

59A-25.005(1)(c), F.A.C.

(c) All providers must have available, at the time of survey, at least one category of equipment that is provided directly,

Interpretive Guideline

Determine which category of equipment is provided directly (providing directly means ordering the equipment from a manufacturer and supplying the equipment directly to the consumer in the home). If there is a question as to whether one category of equipment is provided directly, ask the general manager to produce invoices that show equipment was ordered from a manufacturer rather than provided via a contract.

Here are some examples to show the types of equipment in each category:

-RESPIRATORY MODALITIES - positive airway pressure machines, apnea monitors, oxygen & related respiratory equipment, ventilator equipment

-AMBULATION AIDS - walkers, walking canes, crutches

-MOBILITY AIDS- motorized scooters, wheelchairs, passive motion devices, electrostimulation equipment

-SICKROOM SETUP - hospital beds, lifts, suction machines, phototherapy lights, pressure ulcer care equipment, enteral feeding pumps, infusion pumps, portable home dialysis equipment, trapeze equipment

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filling orders from its own inventory as referenced in Section 400.934(2), F.S. Failure to have, at the time of survey, at least one category of equipment that is provided directly will result in the provider ' s application being denied or the provider ' s license being revoked. A licensed central service center may be determined to meet this standard through the inventory available at its designated distribution center.

-DISPOSABLE SUPPLIES - diabetic, ostomy, urological, wound care

Note: Look for evidence that equipment is provided directly such as the specific inventory itself and recent records showing orders and invoices from manufacturers and/or proof of shipment or delivery of the same product to consumers. If the provider makes custom equipment, look for tools.

At least one CATEGORY of equipment must be available on the premises at the time of survey. If it is not, then denial of the application or revocation of the provider ' s license is required. There can be no plan of correction and no follow-up visit.

ST - O0009 - Business Identification

Title Business Identification

Statute or Rule 59A-25.003(1)(a), F.A.C.

Type Rule

Regulation Definition

Minimum standards: Each home medical equipment provider must:
(a) Have a visible sign with the name of the business, business hours, and a phone number where the business can be contacted during business hours.

Interpretive Guideline

Look for a sign, visible to the public at the location, which includes the required business information.

ST - O0010 - Hours of Operation

Title Hours of Operation

Statute or Rule 400.934(6) FS; 408.806(7)(d) FS

Type Rule

Regulation Definition

400.934(6), F.S.
Ensure that patients are made aware of service hours and emergency service procedures.

Interpretive Guideline

Are the hours of operation the same as those posted on the sign as observed under Tag O-0009 and as listed on the application? How does the provider inform consumers of the service hours?

If the general manager is not on the premises, ask a staff person to contact them to let them know that the Agency is

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408.806(7)(d), F.S.

If a provider is not available when an inspection is attempted, the application shall be denied.

on site and the survey process has started, obtain information from office personnel and interview other staff present to complete as many items as possible. If the general manager never appears during the survey and you are unable to satisfactorily complete the survey, you can either cite those areas you are unable to review or you can indicate that the survey was discontinued and a determination was unable to be made.

If the provider is not open during the hours listed on the current application, the field office should recommend denial of the application to the Home Care Unit. Contact the Unit if you are unsure of the hours of operation.

ST - O0014 - Safety & Infection Control

Title Safety & Infection Control

Statute or Rule 59A-25.003(1)(i), F.A.C.

Type Rule

Regulation Definition

Be able to demonstrate the safety and infection control measures that follow:

1. Procedures that identify safety precautions to be followed in the handling and use of each type of equipment and its related supplies;
2. Equipment is routinely inspected for safety and stability prior to delivery;
3. The electrical adequacy and safety of a home is assessed prior to placing any electrical or electronic equipment, and instructions are provided to consumers regarding applicable precautions and safety measures;
4. Compliance with bedding and mattress reuse regulations;
5. Specific cleaning or sanitizing requirements between usage for each type of equipment according to the manufacturers ' guidelines;
6. Storage of unclean equipment separate from clean equipment;
7. Transportation of unclean equipment separate from clean equipment;
8. Storage of equipment to prevent dust accumulation, water damage, and vermin contact; and

Interpretive Guideline

Ask the general manager to describe the measures taken to meet these requirements including:

The process for inspecting equipment for functionality, intactness and accuracy prior to use;
Instruction given to employees and consumers regarding safety precautions related to equipment and services; and
Policies and procedures related to infection control and manner of storing equipment when clean and unclean.

Examples of positive responses from the provider may be:

The provider can describe and show that clean equipment is stored and transported separately from unclean.
Delivery personnel evaluate electrical adequacy and document that the consumer is informed of any problems before placing electrical or electronic equipment in consumer ' s place of residence. The best documentation procedure would be to have a customer sign a statement informing them of any electrical safety issues;
The provider can describe and show examples of documentation of equipment maintenance and installation (if necessary) in accordance with the manufacturer ' s guidelines.
Delivery personnel clean rental mattresses for bedding curbside before placing it with clean equipment for travel.
Used bedding is cleaned with a germicidal agent before being rented to another consumer.
The provider can describe and show that storage areas are clean, safe and have adequate temperature control.

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9. Equipment is safely maintained and installed based upon the manufacturers ' instructions.

ST - O0015 - Periodic Follow-up

Title Periodic Follow-up

Statute or Rule 400.934(7-8), F.S.

Type Rule

Regulation Definition

As a requirement of licensure, home medical equipment providers shall:

(7) At the time of the initial delivery, set up an appropriate followup home medical equipment service schedule as needed for such times as, but not limited to, periodic maintenance, supply delivery, and other related activities.

(8) Arrange for emergency service after normal business hours; provide refresher and review training for appropriate personnel; establish a system for resolution of complaints and service problems; and provide for timely replacement or delivery of disposable or consumable equipment supplies.

Interpretive Guideline

Ask the provider to identify any rental or purchased equipment with a service contract that needs additional supplies delivered to the consumer after initial set up such as disposable, consumable and/or perishable supplies (for example, batteries).

How is a schedule for replenishing these items determined?

What system is used to ensure supplies are replenished timely?

Examples of positive responses from the provider may be:

Upon initial delivery, personnel determine the need for follow-up. If ongoing supplies and/or maintenance are necessary, the next date for delivery or servicing is established. The provider sends personnel to deliver new supplies or perform maintenance on time.

Note: Periodic follow-up for home dialysis equipment is necessary and all of the probes above for equipment in general would apply. The provider is responsible for the equipment maintenance; however, an End Stage Renal Disease (ESRD) back-up facility would be responsible for patient health care outcome and would monitor the equipment provider with which they have an agreement. The patient should be instructed to rely upon the ESRD for any necessary backup service due to a power outage. Typically, home medical equipment providers are contracted by a manufacturer to provide equipment for peritoneal dialysis treatment and the patient is instructed to call the manufacturer directly when the equipment malfunctions; replacement equipment is shipped by the manufacturer directly to the patient ' s home.

When contacting consumers during survey, ask what happens if a machine/cycler breaks down. Determine if the patient is pleased with the services received.

If a valid complaint is received regarding equipment maintenance, follow up with a POC directed at the home medical equipment provider selling or renting directly to the patient; the provider is responsible for any equipment provided via a contract with a manufacturer; i.e., the provider is held accountable for contracted services provided by a manufacturer.

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If the patient has a complaint regarding the ESRD, refer the complaint to the appropriate ESRD surveyor team to investigate.

ST - O0016 - Servicing Equipment

Title Servicing Equipment

Statute or Rule 400.934(11) FS; 59A-25.003(1)(e) & (3)

Type Rule

Regulation Definition

400.934, F.S.

(11) Maintain and repair directly, or through a service contract with another company, items rented to consumers.

59A-25.003(1)(e), F.A.C.

Be ultimately responsible for the management of all equipment and services even if a contractor is involved.

59A-25.003(3), F.A.C.

Minimum service standards required for equipment are as follows:

- (a) Services for all home medical equipment must be based upon the current recommended manufacturers' standards.
- (b) The provider must prioritize consumer service needs based upon the urgency of the situation. Any equipment utilized to provide a therapy treatment, as prescribed by the consumer's physician, shall require urgent attention. Also, any equipment in general that is completely non-functional shall be serviced with urgency. Any equipment that is functional, but needs minor repair may be serviced in a less urgent time frame. All service requests must be responded to in a timely manner that satisfies the consumer's needs.
- (d) Services may be provided for non-life supporting or life-sustaining equipment during regular business hours. Requests for consumer instruction or any needed repair shall be responded to by telephone within the same working day.

Interpretive Guideline

Ask for a copy of the manufacturers' standards/guidelines for each type of equipment sold by the HME that is serviced. If they provide many different types of equipment that require service, select a sample of a few types of equipment to review. On subsequent surveys sample other equipment.

Review manufacturer standards because they may vary. Compare the manufacturer standards to the provider's maintenance logs and verbal demonstration explaining maintenance to determine if manufacturer recommendations are being followed.

Check samples of consumer's records or equipment maintenance logs to make sure that equipment is being serviced, maintained, or cleaned according to the manufacturers' recommendations.

Ask the provider how they handle consumer calls regarding equipment that may require repair or maintenance. Do they have a system for prioritizing calls? Do they have a timeframe they set for themselves to repair or replace equipment?

Do they repair equipment, do they contract out repair? Under what circumstances will they replace equipment?

Do they meet the requirements in 59A-25.003(3)(b)(d)?

Note: If equipment maintenance is a contracted service the provider should be responsible for monitoring of the contractor with regard to maintenance services. If any contractor supplying equipment is not maintaining the equipment according to manufacturer's guidelines, the provider selling or renting directly to the consumer should be held accountable for any necessary POC. Providers typically keep maintenance logs by utilizing serial numbers on the equipment to identify the specific piece of equipment and dates any maintenance has been performed. Purchased equipment is covered via a manufacturer's warranty and the provider should honor all warranties. Some providers may offer service contracts between themselves and the consumer for purchased equipment.

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The consumer may bring to the provider's place of business any small equipment item requiring consumer instruction or repair.

ST - O0017 - 24-hour & Emergency Service Provision

Title 24-hour & Emergency Service Provision

Statute or Rule 400.934(6 & 8) FS; 59A-003(3)(c) FAC

Type Rule

Regulation Definition

400.934, F.S.

As a requirement of licensure, home medical equipment providers shall:

(6) Ensure that patients are made aware of service hours and emergency service procedures.

(8) Arrange for emergency service after normal business hours

...

59A-25.003(3)(c), F.A.C.

Service must be provided for life-supporting or life-sustaining equipment 24 hours, 7 days per week. Emergency service requests, as referenced in Section 400.934(8), F.S., must be responded to with a telephone call, within 30 minutes and back up service provided at the consumer 's home within two hours or less due to equipment failure or power outages.

Providers must offer assistance regarding registration with emergency management services for consumers who use life-supporting or life-sustaining equipment.

Interpretive Guideline

?

How do they meet the emergency needs of any consumers who live further than 2 hours away? (best response: through contract)

Ask the general manager to describe the emergency process e.g. how does the consumer contact the business after hours? What response does the consumer hear when contacting the after hours number? In what time frame will the business respond to the call?

Note: Providers must have emergency services after normal business hours if they supply equipment that typically requires emergency services. Equipment that typically would require emergency services is listed in the definition above and would also include suctioning equipment per 59A-25.003(2)(a), F.A.C.. In the case of home dialysis, the provider should coordinate emergency dialysis equipment services with the consumer and the ESRD back-up facility.

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ST - O0023 - General Manager

Title General Manager

Statute or Rule 400.934(4&8&10); 59A-25.004

Type Rule

Regulation Definition

400.934, F.S.

As a requirement of licensure, home medical equipment providers shall:

(4) Maintain trained personnel to coordinate order fulfillment and schedule timely equipment and service delivery.

(8) ...provide refresher and review training for appropriate personnel ...

(10) Answer any questions or complaints a consumer has about an item or the use of an item that the consumer purchases or rents.

59A-25.004(1), F.A.C.

General Manager, as defined in Section 400.925(7), F.S.:

(a) Qualifications: A minimum of two years experience in business management or a college degree in business or a health care related field can substitute for the required experience year for year.

(b) Duties: The general manager is responsible for the following areas either directly or by clear delegation in writing:

1. Assuring the maintenance of consumer records including equipment repair and maintenance records as referenced in Section 400.94, F.S.;
2. Maintain job descriptions of staff;
3. Assuring trained and qualified staff essential to the services provided as referenced in Sections 400.934(4), (5), (15), F.S.;
4. Keeping program personnel up to date with health care information and practices;

Interpretive Guideline

Ask the general manager to describe:

all the duties and responsibilities of the job (These must be listed in a written job description and include all duties as required in rule. The areas of direct responsibility of the general manager and/or clear delegation to other specific employee positions must be documented and available for review at time of survey.);

training given to delivery personnel (Who trains them? What are they trained to do?);

training given to intake personnel (Who trains them? What are they trained to do?);

any employee refresher training such as training given by the provider or training offered by a manufacturer of products sold;

the coordination of order fulfillment and equipment service delivery;

how equipment and services are provided appropriately and timely (Who assures this?); and

how the business respond to questions and/or complaints a consumer has about an item or the use of an item.

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5. Directing staff in performance of their duties;
6. Assuring that staff can accommodate consumer ' s language;
7. Assuring an adequate inventory of equipment and supplies to provide consumers currently being served;
8. Assuring that policies are developed and implemented as required in state law and rule;
9. Maintaining and updating procedure manuals related to business functions;
10. Maintain customer service complaint records containing the specifics related to the complaint and how the complaint was resolved as referenced in Sections 400.934(8) and (10), F.S.;
11. Evaluating services, and personnel;
12. Establishing and maintaining effective channels of communication;
13. Maintaining training manuals and records verifying all training that personnel has received or is scheduled to receive thus assuring staff development including orientation, in-service education, and continuing education;
14. Assuring adequate staff supervision during all service hours.

ST - O0024 - Delivery Personnel

Title Delivery Personnel

Statute or Rule 400.934(5-6&8); 59A-25.003(1)(c&h) &

Type Rule

Regulation Definition

400.934, F.S.

As a requirement of licensure, home medical equipment providers shall:

(5) As necessary in relation to the sophistication of the equipment and services being provided, ensure that delivery personnel are appropriately trained to conduct an environment and equipment compatibility assessment; appropriately and

Interpretive Guideline

Ask for a driver's license from delivery personnel. Ask what kind of vehicle is used to deliver the equipment. The license must be appropriate for the vehicle being driven. [A regular operators license is needed if the vehicle weight is between 2,000 - 8,000 lbs.; A class " C " (Chauffeurs) license is needed if carrying hazardous material e.g. oxygen; class " D " license is required for a vehicle over 8,000 lbs. but less than 26,000 lbs.];

Ask delivery personnel if they are able to effectively communicate any instructions, invoices or any paperwork given to the consumer.

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safely set up the equipment; instruct patients and caregivers in the safe operation and client maintenance of the equipment; and recognize when additional education or followup patient compliance monitoring is appropriate.

(6) Ensure that patients are made aware of service hours and emergency service procedures.

(8) ... provide for timely replacement or delivery of disposable or consumable equipment supplies.

59A-25.003(1), F.A.C.

Each home medical equipment provider must:

(c) Provide management and consumer instruction regarding the use of home medical equipment requiring services, as referenced in Section 400.925(11), F.S. Delivery services include transportation of equipment and supplies to and from consumer homes, equipment setup, and record keeping.

(h) Provide the consumer with user instructions as required in Section 400.934(13), F.S.

59A-25.004(3), F.A.C.

Delivery personnel:

(a) Qualifications: A driver ' s license as required by law for the vehicle being driven and the physical capacity to handle the equipment assigned. Delivery persons must be able to accommodate the consumer ' s language and have the ability to work without continuous direct supervision.

(b) Training: Delivery and equipment service staff shall have successfully completed a documented training program covering all components of their assigned jobs including training for each type of equipment they are responsible for delivering.

(c) Duties: Delivery personnel are responsible for providing safe and clean transport of equipment and supplies to and from consumer homes, setting up equipment safely, and record keeping of the equipment delivered. They must provide in

Ask if they have ever received any initial or refresher training provided via the manufacturer or any on the job training in relation to the equipment they deliver and set up;

Ask them to describe how they set up equipment;

Ask how they keep a record of equipment delivered or set up;

Ask them to show you what they leave with the consumer that provides the consumer with a phone number for the HME provider and a phone number to use in case of an emergency;

Ask what they inspect to determine environmental compatibility; e.g., equipment that requires electricity requires grounded outlets; (they would need a ground meter sensor to plug in the outlet to check this);

Ask what instructions are given to the consumer verbally and in writing regarding how the equipment functions safely;

Ask what instructions are given regarding how to contact the provider during regular business hours or after hours if emergency service is necessary (providers may not offer emergency services if they do not supply equipment that requires emergency services (see tag O-0017);

Ask what verbal communication takes place between the delivery person and the consumer regarding any future services to be done in the home setting, e.g., how often will the provider need to return to the home to monitor the equipment?

Ask if they have consumers that speak different languages, e.g., Spanish, English, and if so can they communicate instructions to consumers verbally and do they provide any necessary written instructions in the specific language of the consumer.

Documentation of training provided to delivery personnel must be identified in the employee ' s personnel file to avoid a citation.

Note: Some rental equipment will need service on a regularly scheduled basis such as life-supporting or life-sustaining equipment, e.g., infusion and oxygen therapy. Rental equipment such as hospital beds and wheelchairs will not need service on a set scheduled basis.

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writing to the consumer a telephone number for use during business hours and an emergency number for after business hours when life supporting or life sustaining equipment is provided.

ST - O0025 - Intake Coordinator

Title Intake Coordinator

Statute or Rule 400.934(15) F.S.

Type Rule

Regulation Definition

(15)(a) Designate appropriate staff as intake coordinators, and ensure that order intake personnel are appropriately trained in the types of equipment and products, commonly occurring medical conditions, service procedures, third-party billing, and insurance requirements and coverage.

(b) Train intake coordinators in a basic understanding of the following areas: dealing with patient and caregiver needs; other, nonhome medical equipment provider services as they relate to home medical equipment services and home care patient crisis management.

Interpretive Guideline

Ask the intake person to describe:

What training they receive upon initial orientation;

What equipment products the business sells and what services are offered with the products (if they are able to explain this to you they should also be able to share this information with a consumer).

What response do they give to the consumer who calls to report what they believe to be a patient crisis, e.g., do they ask the consumer specific questions to determine if the crisis is something the HME provider can assist with or perhaps determine that it is a serious enough crisis to have the patient call 911.

Note: Some providers may not use the term " intake coordinator " ; the responsibilities are required regardless of the job title used.

ST - O0026 - Licensed Health Care Professionals

Title Licensed Health Care Professionals

Statute or Rule 59A-25.004(2), F.A.C.

Type Rule

Regulation Definition

Licensed health care professionals, such as respiratory therapists, certified respiratory therapy technicians, registered nurses, and licensed practical nurses that may be on staff or contracted with as needed for service provision:

Interpretive Guideline

Ask the general manager if they have any licensed health care professionals working for the home medical equipment business. If they do, ask to see a copy of their professional license to make sure it is current;

Ask to see a copy of the job description of any licensed health care professional to see that it describes their required

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(a) Qualifications: Current professional license(s).
(b) Training: Clinical staff must have required experience or training relative to the specific service they are providing.
(c) Duties: Provider policies must clearly identify that the respective duties of each type of clinical professional worker are within the scope of the described clinical responsibilities.

duties and that the duties are within the scope of their practice act to perform; and

Ask to see if the licensed health care professional has had any additional training or education related to their responsibilities working with the home medical equipment provider.

ST - O0027 - Maintenance Personnel

Title Maintenance Personnel

Statute or Rule 59A-25.004(4), F.A.C.

Type Rule

Regulation Definition

59A-25.004(4), F.A.C.

Maintenance personnel:

(a) Qualifications: The ability to maintain and coordinate the repair of all equipment and to work without continuous direct supervision.
(b) Training: Attend any training required by the manufacturer regarding equipment maintenance.
(c) Duties: Coordinate maintenance of equipment, complete and sign maintenance logs that verify equipment has been maintained and repaired as required by manufacturer standards.

Interpretive Guideline

Ask maintenance personnel to demonstrate that they meet qualifications by asking them to describe:
How he/she maintains and coordinates repair of equipment;

Any required manufacturer training or on the job training provided in relation to any equipment maintained, e.g., establishment and coordination of records of maintenance or repairs;

Is there a maintenance log identifying equipment that goes into the home that requires maintenance due to any rental agreement or any maintenance contract for purchased equipment? Ask to see these logs to verify that personnel have maintained equipment as directed by the manufacturer.

Note: Maintenance logs are generally kept by using the serial number on the equipment.

ST - O0031 - Filing for Third Party Payment

Title Filing for Third Party Payment

Statute or Rule 400.934(17), F.S.

Type Rule

Regulation Definition

Upon request by the consumer or as otherwise required by

Interpretive Guideline

How do they handle questions and concerns from the consumer regarding filing insurance or what steps are taken to

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state law and rules, or federal law and regulations, assist consumers with meeting the necessary filing requirements to obtain third-party payment to which a consumer may be entitled.

file third party payment?

ST - O0032 - Resolution of Complaints

Title Resolution of Complaints

Statute or Rule 400.934(8), F.S.

Type Rule

Regulation Definition

As a requirement of licensure, home medical equipment providers shall:
(8) ... establish a system for resolution of complaints and service problems...

Interpretive Guideline

Ask the general manager or other staff person in charge:

In the event a consumer is not satisfied with the resolution offered by an employee, are they given the option of talking to the general manager?

How are complaints regarding the equipment and services handled, e.g., malfunctioning, unclean, non-usable? Will the equipment be repaired or replaced as soon as reasonably possible? Is the consumer notified of when the equipment will be replaced or repaired?

How does the provider handle complaints from consumers about HME personnel? Do they interview the staff member? Will the consumer receive a follow up call to settle the complaint?

If an error in billing is found will the account be audited will the billing be adjusted? Will the consumer receive an explanation of all charges and payments posted?

How are delivery service complaints handled? Is the source of the complaint investigated and the issue settled with the consumer?

Note: Providers may use other terms to refer to complaints such as "Incident Reports" or "Opportunities for Improvement."

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ST - O0033 - Personnel Records

Title Personnel Records

Statute or Rule 400.934(16); 59A-25.003(1)(b)

Type Rule

Regulation Definition

400.934, F.S., As a requirement of licensure, home medical equipment providers shall:

(16) Establish procedures for maintaining a record of the employment history, including background screening as required by ss. 400.953 and 408.809(1) and chapter 435 of all home medical equipment provider personnel. A home medical equipment provider must require its personnel to submit an employment history to the home medical equipment provider and must verify the employment history for at least the previous 5 years, unless through diligent efforts such verification is not possible. There is no monetary liability on the part of, and no cause of action for damages arising against a former employer, a prospective employee, or a prospective independent contractor with a licensed home medical equipment provider, who reasonably and in good faith communicates his or her honest opinions about a former employee ' s job performance. This subsection does not affect the official immunity of an officer or employee of a public corporation.

59A-25.003(1), F.A.C.

Each home medical equipment provider must:

(b) Maintain personnel records that must include the following: employment history for the past 5 years, proof of background screening including a signed copy of the good moral character form and a license of any professional that may work from that location. A distribution center will not be required to maintain personnel records but its central service

Interpretive Guideline

Review a sample of at least two employee files.

Do they contain a 5-year work history either via the employment application, resume or some other means?

Do the files include proof of required background screening?

59A-25.005(2), F.A.C.

Complaint investigations:

(a) ... Distribution centers will be allowed forty-eight hours to obtain patient or personnel records from their central service center and to submit the records to the area office when related to a complaint investigation.

Cross reference tag O-Z815 background screening; PROHIBITED OFFENSES

Note: Review the detailed background-screening portion of the employee files. The surveyor is not required to return to a provider location for follow up to view any records requested at the time of the initial complaint investigation; instead, it is the responsibility of the provider to get records to the field office address within 48 hours.

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center shall be responsible for maintaining personnel records.

ST - O0034 - Patient Dumping

Title Patient Dumping

Statute or Rule 59A-25.003(1)(d), F.A.C.

Type Rule

Regulation Definition

Coordinate services with another provider in the event the HME cannot ensure the provision of equipment and services as required in Section 400.935(7), F.S.

Interpretive Guideline

What is the provider ' s policy for termination of equipment and/or services? What kind of notice is given to the consumer? Is anything documented in the record? What if the consumer still requires services? Are services from another provider arranged?

Pull two consumer records that were closed within the last six months and review to determine the reason for termination and whether another provider was found if the consumer still needed services.

Cross reference tag O-0041 CONSUMER record retention/transfer

ST - O0035 - Consumer record confidentiality

Title Consumer record confidentiality

Statute or Rule 59A-25.003(4)(b), F.A.C.

Type Rule

Regulation Definition

Consumer information may not be disclosed from the consumer ' s file without the written consent of the consumer, the consumer ' s guardian or the consumer ' s power of attorney. All information received by any employee, contractor or AHCA employee regarding a consumer of the HME is confidential.

Interpretive Guideline

Are records kept in a manner that protects confidentiality?

Is patient consent required to release information?

How are records protected from destruction or unauthorized use?

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ST - O0040 - Consumer Records

Title Consumer Records

Statute or Rule 400.94(1); 400.935; 59A-25.003(3e&4)

FAC

Type Rule

Regulation Definition

400.94(1), F.S.

The home medical equipment provider must maintain, for each patient, a patient record that includes the home medical equipment and services the home medical equipment provider has provided. Such records must contain:

- (a) Any physician ' s order or certificate of medical necessity, if the equipment was ordered by a physician.
- (b) Signed and dated delivery slips verifying delivery.
- (c) Notes reflecting all services and maintenance performed, and any equipment exchanges.
- (d) The date on which rental equipment was retrieved.
- (e) Such other information as is appropriate to specific patients in light of the particular equipment provided to them.

400.935(5), F.S.

Ensuring that the home medical equipment and services provided by a home medical equipment provider are in accordance with the plan of treatment established for each patient, when provided as a part of a plan of treatment.

59A-25.003(3)(e), F.A.C.

Minimum service standards required for equipment are as follows:

- (e) Life-support or life-sustaining equipment and related supplies must be provided to the consumer in the home environment based on initial and periodic reassessments of the consumer ' s equipment needs. Life supporting or life sustaining equipment shall be provided based upon physician orders including any physician order for medically necessary

Interpretive Guideline

If any equipment was ordered by a physician, review consumer records for a plan of care, Certificate of Medical Necessity (CMN form used by Medicare) or physician order that would describe equipment and services ordered; Look for proof of delivery, e.g., signed and dated delivery slips.

Look for records reflecting equipment maintenance that are generally recorded in a maintenance log using serial numbers to identify each piece of equipment.

Note: A home medical equipment provider should be able to describe the service schedule for any equipment sold or rented with a service contract. The provider should be able to verify what he/she describes to the surveyor regarding maintenance schedules by showing the surveyor specific information in the manufacturer's recommended service maintenance guide related to a specific type of equipment and the brand name.

PLAN OF TREATMENT

Ask the general manager for a list of all their patients that are provided with life-supporting or life-sustaining equipment and review 2 files.

Review any plan of treatment, Certificate of Medical Necessity (CMN used by Medicare) or prescription from the physician and compare it to the equipment and services that are being provided by the HME, i.e., the consumer's equipment and services should match the medical documentation;

Determine if equipment and supplies reassessments are done when the plan of treatment or CMN expires for patients that receive life-supporting or life-sustaining equipment; and

Determine if the provider is supplying any medically necessary backup equipment and supplies for life-supporting or life-sustaining equipment prescribed by the physician.

400.925(10), F.S., "Life-supporting or life-sustaining equipment" means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life. Life supporting or life-sustaining equipment includes apnea monitors, enteral feeding pumps, infusion pumps, portable home dialysis equipment, and ventilator equipment and supplies for all related equipment, including oxygen equipment and related respiratory equipment.

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back-up equipment and supplies.

Note: Some providers may not provide life-supporting or life-sustaining equipment. Notice the law states "when provided as a part of a plan of treatment." Unless the equipment is used to support or sustain life, there may not be a plan of treatment.

59A-25.003(4)(a&c), F.A.C.

Consumer records:

(a) A record must be maintained for each consumer that documents the home medical equipment and any services received as required in Section 400.94(1), F.S.

(c) Consumer records must be made available to AHCA representatives when an inspection or a complaint investigation is done.

ST - O0041 - Consumer Record Retention/Transfer

Title Consumer Record Retention/Transfer

Statute or Rule 400.94(2), F.S.; 59A-25.003(4)(d)

Type Rule

Regulation Definition

400.94(2), F.S.

Such records are considered patient records under s. 456.057 and must be maintained by the home medical equipment provider for 5 years following termination of services. If a patient transfers to another home medical equipment provider, a copy of his or her record must be provided to the other home medical equipment provider, upon request.

59A-25.003(4), F.A.C.

Retained records can be stored as hard paper copy, microfilm, computer discs or tapes as long as they are retrievable for use during unannounced inspections or complaint investigations.

Interpretive Guideline

Ask where active and inactive consumer records are stored

How long are inactive consumer records kept and are these readily retrievable for inspection?

Does the provider transfer consumer records to a new provider upon request?

Choose two consumer records that have been placed in the closed files and verify the reason for closure. Providers should not discontinue service to a consumer unless the consumer requests discontinuation of services or the consumer 's physician does not renew an expired prescription or plan of treatment for the service; the record should document the reason for closure.

Cross reference tag O-0034 Patient Dumping

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ST - O0047 - Accept Returns

Title Accept Returns

Statute or Rule 400.934(12), F.S.

Type Rule

Regulation Definition

Accept returns of substandard or unsuitable items from consumers. As used in this subsection, the term " substandard " means less than full quality for the particular item and the term " unsuitable " means inappropriate for the consumer at the time it was fitted or sold.

Interpretive Guideline

How does the business respond to a consumer that states a piece of equipment is unsuitable? Do they accept returns of substandard and unsuitable items?
Ask the provider if they replace rental equipment when it's unsuitable or needs repair.

ST - O0048 - Warranties

Title Warranties

Statute or Rule 400.934(9)&(13) FS; 59A-25.003(1)(f-g)

Type Rule

Regulation Definition

400.934, F.S., As a requirement of licensure, home medical equipment providers shall:

(9) Honor all warranties expressed and implied under applicable state law.

(13) Disclose consumer information to each consumer who rents or purchases items, including all applicable warranty information. This information consists of the provider standards to which the item must conform.

59A-25.003(1), F.A.C.

(f) Honor all express warranties regarding assistive technology devices. The duration of the express warranty must be at least one year after first delivery of the assistive technology device

Interpretive Guideline

Ask if all warranties are honored and if manufacturer warranty information is provided to the consumer.
When sampling consumer records, look for evidence of equipment warranty work done. This may be kept in separate files rather than in consumer records; if so, request to review the files that show warranty work and sample at least two files.
Make sure the provider is honoring the manufacturer warranty on new equipment and is giving at least a 30-day warranty on any used equipment.

Note: Examples of assistive technology devices that are also considered home medical equipment include wheelchairs, motorized scooters, communication devices that enable persons with speech disabilities to speak, transfer devices and specialty beds.

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to the consumer as required in Section 427.803, F.S.
(g) Honor all warranties as required in Section 400.934(9),
F.S., and warranty used equipment at least 30 days.

ST - O0055 - Special needs registry - Assistance

Title Special needs registry - Assistance

Statute or Rule 252.355(1)&(6) FS; 59A-25.006(6) FAC

Type Rule

Regulation Definition

252.355, (1) In order to meet the special needs of persons who would need assistance during evacuations and sheltering because of physical, mental, cognitive impairment, or sensory disabilities, the division, in coordination with each local emergency management agency in the state, shall maintain a registry of persons with special needs located within the jurisdiction of the local agency. The registration shall identify those persons in need of assistance and plan for resource allocation to meet those identified needs.

(2) In order to ensure that all persons with special needs may register, the division shall develop and maintain a special needs shelter registration program. The registration program must be developed by January 1, 2015, and fully implemented by March 1, 2015.

(a) The registration program shall include, at a minimum, a uniform electronic registration form and a database for uploading and storing submitted registration forms that may be accessed by the appropriate local emergency management agency. The link to the registration form shall be easily accessible on each local emergency management agency ' s website. Upon receipt of a paper registration form, the local emergency management agency shall enter the person ' s registration information into the database.

(b) To assist in identifying persons with special needs, home health agencies, hospices, nurse registries, home medical

Interpretive Guideline

Determine if the provider serves any persons with special needs. Persons with special needs are generally people who need help due to being dependent on equipment that requires power such as oxygen concentrators or ventilator equipment. Also, disabled persons who live alone or with other disabled persons are considered special needs persons and may need assistance with any necessary evacuation;

Determine if the provider educates consumers about the need to register with the County Emergency Management Agency in order to receive assistance, should the need to evacuate their home become necessary. It is especially important for consumers using equipment that requires electricity to have a backup plan should the power fail.

Determine if the provider has contacted the County Emergency Management Agency to obtain information on the registration process in each county where they offer equipment. The home medical equipment provider should have information available for consumers on how to register with the County Emergency Management Agency .

Determine if the provider collects registration information from consumers in order to offer assistance with registration for special needs sheltering and evacuation. The County Emergency Management Agency should be notified through the special needs registration process of those consumers who are electricity dependent. If the county does not allow outside persons to submit information and requires direct contact with special needs persons, then the home medical equipment provider should have a copy of the county ' s instructions that states this requirement. Regardless of the individual county ' s process, the provider is still expected to inform consumers who would need assistance in an evacuation of the special needs registry.

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equipment providers, the Department of Children and Families, the Department of Health, the Agency for Health Care Administration, the Department of Education, the Agency for Persons with Disabilities, the Department of Elderly Affairs, and memory disorder clinics shall, and any physician licensed under chapter 458 or chapter 459 and any pharmacy licensed under chapter 465 may, annually provide registration information to all of their special needs clients or their caregivers. The division shall develop a brochure that provides information regarding special needs shelter registration procedures. The brochure must be easily accessible on the division 's website. All appropriate agencies and community-based service providers, including aging and disability resource centers, memory disorder clinics, home health care providers, hospices, nurse registries, and home medical equipment providers, shall, and any physician licensed under chapter 458 or chapter 459 may, assist emergency management agencies by annually registering persons with special needs for special needs shelters, collecting registration information for persons with special needs as part of the program intake process, and establishing programs to educate clients about the registration process and disaster preparedness safety procedures. A client of a state-funded or federally funded service program who has a physical, mental, or cognitive impairment or sensory disability and who needs assistance in evacuating, or when in a shelter, must register as a person with special needs. The registration program shall give persons with special needs the option of preauthorizing emergency response personnel to enter their homes during search and rescue operations if necessary to ensure their safety and welfare following disasters.

59A-25.006(6), F.A.C.

Home medical equipment providers must assist consumers receiving HME services who would need assistance and

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sheltering during evacuations because of physical, mental, cognitive impairment, or sensory disabilities in registering with the local emergency management agency, as required in Section 252.355(1), F.S., and as determined by the established procedures of the local emergency management agency related to special needs registration.

(a) Each home medical equipment provider must, pursuant to Section 400.934 and 252.355, F.S., inform consumers and consumer caregivers, by the best method possible as it pertains to the person ' s disability, of the special needs registry and procedures for registration at the special needs registry maintained by their county emergency management office.

(b) If the consumer is to be registered with the special needs registry, the home medical equipment provider must assist the consumer with registering, pursuant to Sections 400.934 and 252.355, F.S., and the established procedures of the local emergency management agency. The home medical equipment provider must document in the consumer ' s file if the consumer plans to evacuate or remain at home and if the consumer ' s caregiver or family can take responsibility during the emergency for equipment services normally provided by HME staff or independent contractors referred by the home medical equipment provider or if the home medical equipment provider needs to make referrals in order for equipment services to continue. If the consumer is also receiving services through any other licensed health care provider or federal or state funded program designated in Section 252.355, F.S., to help clients register with the special needs registry, then the home medical equipment provider will check with the other service provider or program case manager to verify if the consumer has already been registered. If so, a note will be made in the consumer ' s file by the home medical equipment provider that the consumer ' s need for registration has already been reviewed and handled by the other provider or program. Home medical equipment providers are not required to assist

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consumers residing in skilled nursing facilities, assisted living facilities or adult family care homes with special needs registration as those licensed facilities are responsible for evacuation and alternative sheltering of their clients.

(c) The collected registration information must be furnished to the county emergency management agency pursuant to Section 400.934, F.S., and as determined by the established procedures of the local emergency management agency related to special needs registration.

ST - O0056 - Special needs registry - Consumer records

Title Special needs registry - Consumer records

Statute or Rule 59A-25.006(6)(b), F.A.C.

Type Rule

Regulation Definition

If the consumer is to be registered with the special needs registry, the home medical equipment provider must assist the consumer with registering, pursuant to Sections 400.934 and 252.355, F.S., and the established procedures of the local emergency management agency. The home medical equipment provider must document in the consumer ' s file if the consumer plans to evacuate or remain at home and if the consumer ' s caregiver or family can take responsibility during the emergency for equipment services normally provided by HME staff or independent contractors referred by the home medical equipment provider or if the home medical equipment provider needs to make referrals in order for equipment services to continue. If the consumer is also receiving services through any other licensed health care provider or federal or state funded program designated in Section 252.355, F.S., to help clients register with the special needs registry, then the home medical equipment provider will check with the other service provider or program case manager to verify if the consumer has already been registered. If so, a note will be

Interpretive Guideline

If the provider serves persons on the special needs registry, check a sample of those consumers ' files for documentation of:

- assistance provided by the home medical equipment provider or another provider or program with the special needs registration
- whether the consumer intends to evacuate or remain at home who will take responsibility for services normally provided by the home medical equipment provider, such as family or other caregivers, or if the provider needs to continue services

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made in the consumer ' s file by the home medical equipment provider that the consumer ' s need for registration has already been reviewed and handled by the other provider or program. Home medical equipment providers are not required to assist consumers residing in skilled nursing facilities, assisted living facilities or adult family care homes with special needs registration as those licensed facilities are responsible for evacuation and alternative sheltering of their clients.

ST - O0060 - Emergency management plan - Preparation

Title Emergency management plan - Preparation

Statute or Rule 400.935(9) 59A-25.006(1)

Type Rule

Regulation Definition

400.935(9), F.S.

Preparation of the comprehensive emergency management plan under s. 400.934 and the establishment of minimum criteria for the plan, including the maintenance of patient equipment and supply lists that can accompany patients who are transported from their homes. Such rules shall be formulated in consultation with the Department of Health and the Division of Emergency Management.

59A-25.006(1), F.A.C.

Pursuant to Section 400.934(20)(a), F.S., each home medical equipment provider must prepare and maintain a written comprehensive emergency management plan, that meets the minimum criteria in these rules and the Comprehensive Emergency Management Plan (CEMP) Format for Home Medical Equipment (HME) Providers, AHCA Form 3110-1019, December 2006, incorporated by reference. This document is available from the Agency for Health Care Administration at <http://ahca.myflorida.com> under Licensing & Certification, Home Medical Equipment Provider. The

Interpretive Guideline

Does the provider have a written comprehensive emergency management plan prepared following the required Comprehensive Emergency Management Plan (CEMP) Format for Home Medical Equipment (HME) Providers, AHCA Form 3110-1019, Dec. 06?

Are all sections of the format completed appropriately or has the provider adequately explained on the plan why a specific section is not applicable to its business?

A CEMP must be prepared by every licensed home medical equipment provider.

Refer to Tag O-0017 for definition and discussion of life-supporting or life-sustaining equipment. Licensing & Certification should read Licensing & Regulation. PENDING RULE REVISION

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CEMP Format contains the minimum criteria that must be included in each home medical equipment provider emergency management plan, as required in Section 400.934(20), F.S. The plan must describe how the home medical equipment provider establishes and maintains an effective response to emergencies and disasters. The completed plan will be e-mailed or mailed to the local county health department for each county listed on the home medical equipment provider's license as required in Section 400.934(20)(b), F.S., unless the county health department does not require submission of home medical equipment provider emergency management plans per Section 381.0303(7), F.S.

ST - O0061 - Emergency management plan - Local review

Title Emergency management plan - Local review

Statute or Rule 400.934(20)(b), F.S.; 59A-25.006(1)

Type Rule

Regulation Definition

400.934(20)(b), F.S.
The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders when necessary. The county health department shall complete its review to ensure that the plan is in accordance with the criteria in the Agency for Health Care Administration rules within 90 days after receipt of the plan. If a home medical equipment provider fails to submit a plan or fails to submit requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home medical equipment provider that such failure constitutes a deficiency, subject to a fine of \$5,000 per occurrence. If the plan is not

Interpretive Guideline

Note: The "County Health Department Points of Contact for CEMP Review" are listed on the Agency's website at ; click on 'Licensing & Certification' and then 'Home Medical Equipment Provider.'

Due to funding constraints, county health departments have the option to (1) require submission of home medical equipment providers' plans to review for compliance; (2) require submission but not review for compliance; or (3) not require submission at all. It is the provider's responsibility to contact the county health department for each county listed on its license in order to determine and document whether the plan should be submitted to that county and, if submission is required, whether the county health department will be reviewing the plan for compliance.

Has the provider submitted a completed Comprehensive Emergency Management Plan (CEMP) Format for Home Medical Equipment (HME) Providers, AHCA Form 3110-1019, Dec. 06 to the county health department for each county listed on its license that requires submission?

Note: If the provider has not submitted its plan to a county health department that requires submission or has not submitted requested information or revisions to a county health department that reviews plans for compliance within 30 days of written notice, then the surveyor must cite and require correction. If not corrected, the field office may

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submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

complete a Request for Sanction in the amount of a \$5,000 fine.

59A-25.006(1), F.A.C.

... The completed plan will be e-mailed or mailed to the local county health department for each county listed on the home medical equipment provider ' s license as required in Section 400.934(20)(b), F.S., unless the county health department does not require submission of home medical equipment provider emergency management plans per Section 381.0303(7), F.S.

Remember, a CEMP must be prepared by every licensed home medical equipment provider regardless of whether it will be reviewed by any local county health department.

ST - O0062 - Emergency management plan - Annual update

Title Emergency management plan - Annual update

Statute or Rule 400.934(20)(a), F.S.; 59A-25.006(2)

Type Rule

Regulation Definition

400.934, F.S., As a requirement of licensure, home medical equipment providers shall:

(20)(a) Prepare and maintain a comprehensive emergency management plan that meets minimum criteria established by agency rule under s. 400.935. The plan shall be updated annually and shall provide for continuing home medical equipment services for life-supporting or life-sustaining equipment, as defined in s. 400.925, during an emergency that interrupts home medical equipment services in a patient ' s home.

59A-25.006(2-3), F.A.C.

(2)The home medical equipment provider must review its emergency management plan on an annual basis, make any substantive changes and inform their staff of those changes. For the purposes of this section, ' substantive changes ' would include, but not be limited to, change of address, change of

Interpretive Guideline

Is the CEMP reviewed and updated annually? If 'substantive changes' as defined in this standard have been made, were those changes reported to each county health department reviewing entity that requires submission and each county emergency management office designated on the license?

CROSS REFERENCE tag O-0004 Change of GENERAL MANAGER

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administrative staff who are responsible for coordinating the home medical equipment provider ' s emergency response or their contact telephone numbers and change of type of equipment or equipment services provided.

(3) The substantive changes as defined in subsection 59A-25.006(2), F.A.C., must be reported to the county emergency management office and to the county health department. For home medical equipment providers with multiple counties on their license, the changes must be reported to each county health department and each county emergency management office designated on the license. The telephone numbers must include numbers where the coordinating staff can be contacted outside of the home medical equipment provider ' s regular office hours. All home medical equipment providers must report these changes, whether their plan has been previously reviewed or not, as defined in subsection (1).

ST - O0063 - Emergency mgmt plan - Change of ownership

Title Emergency mgmt plan - Change of ownership

Statute or Rule 59A-25.006(4), F.A.C.

Type Rule

Regulation Definition

When a home medical equipment provider goes through a change of ownership, the new owner must review the emergency management plan and make any substantive changes, including changes noted in subsection (3). Those home medical equipment providers will need to report any substantive changes in their plans to the reviewing entity in subsection (1).

Interpretive Guideline

If a CHOW has occurred was the CEMP reviewed and updated? Were substantive changes including, but not limited to, change of address, change of administrative staff who are responsible for coordinating the home medical equipment provider ' s emergency response or their contact telephone numbers and change of type of equipment or equipment services provided reported to the local county health department reviewing entity in each county listed on the license?

CROSS REFERENCE tag O-Z812 Change of ownership

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ST - O0064 - Emergency Management Plan - Prioritized list

Title Emergency Management Plan - Prioritized list

Statute or Rule 400.934(21), F.S.

Type Rule

Regulation Definition

Each home medical equipment provider shall maintain a current prioritized list of patients who need continued services during an emergency. The list shall indicate the means by which services shall be continued for each patient in the event of an emergency or disaster, whether the patient is to be transported to a special needs shelter, and whether the patient has life-supporting or life-sustaining equipment, including the specific type of equipment and related supplies. The list shall be furnished to county health departments and local emergency management agencies upon request.

Interpretive Guideline

Does the provider maintain a current prioritized list of patients who will need continued services during an emergency?

How does the provider keep the list current?

Does the prioritized list indicate:

- how services will be continued;
- whether patient is to be transported to the special needs shelter;
- and, if applicable, the specific type of life-supporting or life-sustaining equipment and related supplies?

If the provider serves a county that requests this list be supplied to local emergency management personnel, was it furnished?

ST - O0065 - Emergency management plan - Implementation

Title Emergency management plan - Implementation

Statute or Rule 59A-25.006(5) & (7-9) FAC

Type Rule

Regulation Definition

(5) In the event of an emergency, the home medical equipment provider must implement the emergency management plan pursuant to Section 400.934(20), F.S.

(7) The home medical equipment provider must provide the same type and quantity of equipment services to its consumers, which must include those being served in assisted

Interpretive Guideline

If an emergency situation that could have impacted this provider has occurred or has threatened the geographic service area since the last survey, check for documentation that the CEMP was implemented.

- Was staff informed that emergency response measures were initiated?
- Is there evidence of communication between staff and local emergency management personnel?
- Was there an alternative means of communication if phone service was down?
- Were patients, who were in need of continued medical equipment services and supplies, prioritized appropriately

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living facilities and adult family care homes, who evacuate to special needs shelters which were being provided prior to evacuation, pursuant to Section 400.934(20)(a), F.S. Home medical equipment providers are not required to continue to provide services to consumers in emergency situations that are beyond their control and that make it impossible to provide services, such as when roads are impassable or when consumers do not go to the location specified in their consumer records.

(8) If the home medical equipment provider is unable to provide equipment services to consumers who are special needs registry patients, including any assisted living facility and adult family care home special needs registry patients, then the provider will make reasonable efforts to find another resource for the consumer, pursuant to Section 400.934(20)(a), F.S. This would include arranging for services for consumers who have been forced to relocate outside of the geographic service area of the home medical equipment provider.

(9) During emergency situations, when there is not a mandatory evacuation order issued by the local county emergency management office, some consumers, registered pursuant to Section 252.355, F.S., may decide not to evacuate and will stay in their homes. The home medical equipment provider must establish procedures, prior to the time of an emergency, which will delineate to what extent the provider will continue to arrange for essential equipment services during and immediately following an emergency pursuant to Section 400.934(20)(a), F.S.

and contacted?

- Did staff attempt to follow procedures in the plan including providing the same level of care to patients who went to special needs shelters?
- Were procedures for continuing home medical equipment services for life-supporting or life-sustaining equipment, as defined in s. 400.925, during an emergency that interrupts home medical equipment services in a patient's home followed?

Were written agreements with other organizations implemented, if necessary, to continue essential care or services?