



Posey Company

5635 Peck Road

Arcadia, CA 91006-0020 USA

Toll Free: (800) 44-POSEY or (800) 447-6739

Web: www.posey.com

FAQ No.: 25

FAQ: Can Posey Company Sell Restraints Direct To Individuals or Non-Medical Facilities?

No. Restraints are “legend” medical devices that require a label stating “Caution: Federal law restricts this device to sale by or on the order of a physician”.

Federal Register Volume 61 Number 43, dated March 4, 1996, states that the FDA issued a letter to manufacturers in February 1992 stating that “FDA considered restraints to be prescription devices which must bear a prescription legend as prescribed in 801.109 (21 CFR 801.109) to help ensure appropriate medical intervention in the application and use of restraints.”

California law requires restraint manufactures to restrict the sale of restraints to licensed medical facilities, pharmacies, and licensed medical device retailers.

See California State Board of Pharmacy letter dated May 3, 1991 for authority.

Definition of Restraint: A restraint is any method of physically restricting a person’s freedom of movement, physical activity, or normal access to his or her body. FDA, CMS and JCAHO all state that restraints should only be used when the resident/patient is in danger of injury to himself or others, and the restraint can be shown to improve functional status. When a restrictive device is required, the least restrictive product should always be selected.

Products that **may not** be sold to an Individual are restraint products that have the “legend” that states: “Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.” Such as Bed Enclosure Safety Systems, Vests, Jackets, Limb Holders, Belts, Etc...

ACCEPTABLE PRODUCTS FOR DIRECT SALE:

The Posey Company carries many products that can be sold to individuals that are restraint free and that will allow the individual to move freely. These products include Positioning Rolls, Lateral Stabilizers, Comfy Seat Huggers, Foot Hugger, Slim Supports, Orthotic Seating System, Sitter Alarm, Personal Alarm, Siderails, Arm Rest, Self Releasing Belts, Lap Top Trays, a variety of cushions, slippers and any other product that does not secure to any part of the patient’s body or any part of the wheelchair or bed that will prevent the patient from moving freely.

REFER INDIVIDUAL TO DEALER:

If any individual requests to purchase a restraint, by definition of a restraint stated above, please refer them to a supplier that is authorized to carry Posey products by entering their zip code in our customer database. This will help you locate the nearest medical device retailer in their area.

The Posey Company will bill to and ship to the supplier.

LITERATURE REFERENCES:

For additional information on this subject, refer to Posey literature I9200 and M5021.

For complete cleaning and use instructions for all Posey products, please refer to package insert instructions accompanying each product. Copies of all package insert instructions are available on the Posey website at www.posey.com.

We hope that this answers your questions. If you have any further questions, please feel free to call Posey Customer Service at (800) 44-Posey or (800) 447-6739.

CALIFORNIA STATE BOARD OF PHARMACY

1020N STREET. SACRAMENTO. CA 95814

TELEPHONE: (916) 445-5014



May 3, 1991

Dear Manufacturer:

As you may know, on July 1, 1991, California will require all firms that furnish, display or store prescription or "legend-devices to be licensed as medical device retailers in California if they are not already licensed as pharmacies. This licensing requirement will apply to all non-pharmacy providers who sell legend devices to patients and/or health care professionals.

The California State Board of Pharmacy is mandated to implement and enforce the requirements of the new law. In charge of any medical device retailer must be registered pharmacist, or a non-pharmacist who is certified by the board at meeting specific requirements relating to training and experience.

I am writing this letter to you to advise you of these requirements. If you are shipping legend devices to an unlicensed firm, we ask that you discontinue from doing so after July 1, 1991, until the firm is appropriately licensed by us as a medical device retailer.

Please do not hesitate to contact the Los Angeles office or Sacramento office (916) 324-5014 should you desire additional information.

Truly,

Patricia F. Harris
Executive Officer