Medical device retailers or any home care provider who provides respiratory care equipment or respiratory care in the home are subject to the following regulations. Any person or employer who is in violation of these regulations should be reported to the Respiratory Care Board of California.

- **Unlicensed Personnel (UP)** must be employed by a Home Medical Device Retail Facility or Home Health Agency licensed by the Department of Health Services.

- UP must have regular training and be competency tested to each service and equipment-type by either a licensed respiratory care practitioner (RCP) or other qualified licensed personnel. Documentation of such must be retained by the employer for four years.

- The employer must ensure that the patient, the patient’s family, or the patient’s caregiver(s) are advised prior to or at the time equipment or supplies are delivered, that a RCP or other qualified licensed personnel, shall provide follow up checks upon their request or in accordance with the plan of care.

- UP **may** deliver equipment and supplies.

- UP **may** instruct the patient, the patient’s family or the patient’s caregiver(s) on how to order equipment and supplies and the telephone number to call 24 hours a day, 7 days a week, in case of emergency in which a live person will be available to respond.

### All Respiratory Care Devices
(except certain oxygen delivery systems and prefilled cylinders requiring simple mask and cannula)

As it relates to the following equipment and supplies for:
- positive airway pressure (with or without a back-up rate) devices
- intermittent positive pressure breathing devices
- ventilatory devices
- nasotracheal or tracheal suctioning devices
- apnea monitors and alarms
- tracheostomy care devices
- respiratory diagnostic testing devices and supplies, including but not limited to pulse oximetry, CO2 monitoring, and spirometry devices
- pulse-dose type or demand conserving oxygen delivery devices or high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen
- any other respiratory care equipment and supplies not otherwise identified

- UP **may** set up equipment to the extent that the set-up is not dependent upon or influenced by any written or oral communication with the patient or the patient’s family, caregiver(s) or physician (with the exception of identifying a physical location in the home for set-up).

- UP **may** provide instruction to the patient, the patient’s family or the patient’s caregiver(s) limited to the mechanical operation of the equipment (e.g. switch, knob, and dial locations) or the general use of equipment or supplies.
• UP are **prohibited** from setting up equipment to an extent that it constitutes patient care (such as applying any device to the patient or making any adjustment or taking any action that requires or is dependent upon or influenced by any written or oral communication with the patient or the patient's family, caregiver(s) or physician)

• UP are **prohibited** from providing any instruction to an extent that it constitutes patient care (such as instruction in the operation or use of the equipment for the purpose of deriving an intended medical benefit or instruction in the clinical application of equipment and/or supplies)

• UP are **prohibited** from performing any level of clinical assessment of the patient

• UP are **prohibited** from directly engaging in any discussion of clinical care plans, therapy, prescriptions, or clinical application

• UP are **prohibited** from touching a patient for the purposes of making an assessment or placing any device upon the patient

• UP are **prohibited** from providing any service that is not expressly authorized by the Respiratory Care Board

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### Oxygen Delivery Systems & Prefilled Cylinders

As it relates to oxygen delivery systems and prefilled cylinders, with the exception of pulse-dose or demand conserving oxygen systems and high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen:

• UP **may** instruct the patient, the patient's family or the patient's caregiver(s) in the proper and safe operation of oxygen equipment including:
  (i) equipment set-up for the purpose of making the equipment patient-ready
  (ii) connecting disposable tubing, cannulas, and masks
  (iii) verification of oxygen flow
  (iv) demonstration to the patient of prescribed flow rate(s)
  (v) connection and cleaning of oxygen humidifying equipment and devices
  (vi) use of portable back-up oxygen cylinders and equipment
  (vii) removal and disposition of disposable tubing, cannulas, and masks

• UP **may** use a mock, self-demonstration as a method of instruction

• UP **may** conduct regular in-home evaluations and gather information from the patient and home setting pertaining to the set-up, instruction, and provision of information as described in this subdivision for the use of the prescribing physician

• UP are **prohibited** from direct administration of home oxygen

• UP are **prohibited** from handling or adjusting home oxygen equipment while it is in use by the patient or on the patient

• UP are **prohibited** from touching the patient or placing any device upon the patient while engaged in the set-up and instruction of equipment, including, but not limited to, applying a cannula or performing an oximetry evaluation or oxygen saturation test

• UP are **prohibited** from directly engaging in any discussion of clinical care plans, oxygen therapy or any modifications of physician prescribed equipment, dosages, or instructions or clinical applications