

## Home Respiratory Care Review

April 2005

### SUMMARY

In 2001, the Respiratory Care Board of California (Board) underwent a review by the Joint Legislative Sunset Review Committee (JLSRC) and noted its concern for the lack of regulatory oversight for respiratory care provided in the home. In response, recommendations made by the JLSRC included in its 2002 recommendations to support the Board's effort to review the function and skill of currently unlicensed technicians and further study to determine the need for regulation of these technicians. This paper documents the Board's findings.

The Board's review has found a growing trend towards home care and the home use of sophisticated medical devices by unqualified caregivers. As a result, patient safety and the clinical effectiveness of medical devices, as they pertain to respiratory care, has declined, jeopardizing respiratory patients' health, safety, and welfare. In addition, reports of fraud are prevalent among many home care providers.

Many sophisticated medical devices used for respiratory care such as ventilators, continuous positive airway pressure devices, respiratory disease management devices, apnea monitors and low air loss continuous pressure management devices, require extensive education and instruction or the consequences can be detrimental. The use of these respiratory care devices is governed by the Respiratory Care Practice Act and requires licensure as a respiratory care practitioner, other qualified licensed personnel, or by a person exempted from the Act. Self-care by the patient or the gratuitous care by a friend or member of the family is one of those exemptions.

Personnel entering homes in support of the home care patient include respiratory care practitioners (RCPs), registered nurses (RNs), vocational nurses, home health aides, and other non-licensed personnel including equipment delivery personnel. There is a vast range of education and experience among these personnel, from people having no familiarity with patient care and/or medical equipment to those that have been educated, trained, and competency tested in patient care and sophisticated respiratory equipment.

Currently in California, home care regulation is limited to Home Medical Device Retail Facilities (HMDRFs) and Home Health Agencies (HHAs). Neither component recognizes the need for formal education, training and competency testing as it pertains to respiratory care and the use of respiratory medical devices.

There are an estimated 3600 HMDRFs in California, regulated by the Department of Health Services (DHS). According to Health & Safety Code, section 111635, the department shall conduct inspections "to determine ownership, adequacy of facilities, and personnel qualifications." However, inspections of "personnel qualifications" is limited to showing evidence that an employee has been "trained" to understand the operation of the device. Generally, evidence of "training" consists of a certificate of completion from either an in-service session or manufacturer's course on specific equipment. There is no requirement to evaluate competency or consider personnel qualifications as it relates to the care or well being of the patient. Further, because licensure of HMDRFs stops at the instruction in the use of equipment, there is no inspection related to personnel qualifications in providing care.

However, the HMDRF unit has been working with the Board by investigating complaints of unlicensed practice at the time of scheduled inspections. Several HMDRFs are employing equipment delivery personnel to perform patient care, including the performance of ventilator checks, diagnostic tests and medication delivery. Equipment delivery personnel are not qualified or authorized to perform any type of clinical assessment or care. There are also numerous reports of fraud emerging specifically that HMDRFs are ordering additional tests without a physician's order and billing for additional and unnecessary equipment. Many HMDRFs have been

using equipment delivery personnel to conduct these respiratory diagnostic tests which are the basis for renting additional equipment.

Unlike the regulation of HMDRFs, HHAs are mandated to provide patient care. It is believed that regulation of "patient care" has made the unsafe practice of respiratory care less prevalent among Home Health Agencies. The most common complaint received regarding HHAs is that the staff are not familiar with respiratory medical equipment and are not educated to respond to unusual situations. Furthermore, the staff are not educated or trained on how to use the medical equipment to allow the patient to receive the most beneficial treatment. HHAs are required to have a RN, or occupational, physical, or speech therapist oversee all treatment plans (within each professional's scope of practice). Generally, a RN will oversee the treatment plan of a patient with respiratory ailments. However, care may be performed by a LVN, home health aide or "other non-licensed personnel."

Another factor to consider is the dispensing of oxygen cylinders, one of the most frequently dispensed devices. There are reports that drivers are delivering oxygen cylinders improperly such as placing tanks next to gas pilot lights. Although the handling of oxygen is not required to be done by a licensed professional, the HMDRF must ensure personnel handling oxygen are trained. Again, nothing more than a certificate of completion is needed for purposes of regulation. Licensed professionals (i.e. RCP, RN, LVN) receive formal education and training on the handling of hazardous materials. There have been several warnings issued in relation to the improper handling of oxygen and medical gas mix-ups resulting in unnecessary fatalities.

The Board is mandated to protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care. It is further mandated that "protection of the public shall be the highest priority for the Respiratory Care Board of California in exercising its licensing, regulatory, and disciplinary functions."

In accordance with its mandates, the Board makes the following recommendations:

- **Respiratory Care Practice Act**  
The Board recommends legislative amendments as a means to provide guidance to the home care industry, through regulation, of what services a "delivery driver" or other unlicensed personnel may perform and under which criteria, as it relates to respiratory care and respiratory care related services.
- **Home Medical Device Retail Facility Act**  
The Board recommends the DHS be given broader regulatory control over HMDRFs who dispense respiratory equipment and/or supplies, require those HMDRFs to hold national accreditation, employ qualified licensed personnel, and notify caregivers and make available 24 hour access to qualified personnel.
- **Home Health Agency Act**  
The Board recommends legislative amendments to provide clarification that a licensed HHA may provide or arrange for respiratory services (as currently done), and provide licensed RCPs as an additional type of licensed personnel that can provide supervision of personnel, allowing HHAs more options in providing optimum care for their respiratory care patients. The proposed amendments do not provide for additional services or costs, but rather provide the ability to use the expertise of a respiratory care practitioner in the plan of treatment when it is within the respiratory care scope of practice.
- **Reimbursement**  
The Board recommends that serious consideration be given to establish provisions for the reimbursement of follow-up patient assessments made through HMDRFs. Currently, HMDRFs are reimbursed for specific types of equipment delivered. Reimbursement for the freight, delivery, transportation, installation, setup and instruction in the use of equipment, and repair, maintenance or routine servicing is inclusive in these flat rates.

The Board believes that providing reimbursement for follow up assessments made by qualified licensed personnel could provide significant savings in health care costs through shorter rental periods and fewer emergency room visits and hospital readmissions.