Karen M. McGovern Deputy Director, Programs and Legal Affairs Division of Professions and Occupations Colorado Department of Regulatory Agencies 1560 Broadway, Suite 1350 Denver, CO 80202 <u>karen.mcgovern@state.co.us</u>

Dear Ms. McGovern:

As a sleep medicine physician in the state of Colorado, and as a member of the American Academy of Sleep Medicine (AASM), I strongly object to the draft, "<u>Rule XXVI. Obstructive Sleep Apnea</u>," which was developed by the Colorado Dental Board's Sleep Apnea Committee and submitted to the Colorado Medical Board for consideration during its upcoming meeting on May 18.

Home sleep apnea testing (HSAT) devices – also referred to in the draft rule as "unattended cardiorespiratory portable monitors" - are approved by the U.S. Food and Drug Administration (FDA) as diagnostic, medical devices, and their use is indicated solely for the diagnosis of obstructive sleep apnea (OSA) by physicians. Coverage for HSAT is provided by the Centers for Medicare and Medicaid Services (CMS) and private medical insurers when the test is performed by a physician at an accredited sleep facility. HSAT has no other indications for use.

The use of an HSAT device, like any other medical device, is outside the scope of practice of dentistry. However, the draft rule indiscriminately allows dentists to dispense these medical devices to patients (A.2) and use them routinely in clinical practice, including to "assess" the interim results of treatment (B.3). A dentist who uses an HSAT device to assess a patient for the presence or absence of sleepdisordered breathing is in essence making a medical diagnosis. Clearly, the draft rule would permit dentists to practice medicine.

The draft rule, as proposed by the Colorado Dental Board, unacceptably violates the professional boundaries established by the Colorado Medical Practice Act and the Dental Practice Act. By blurring the lines between dentistry and medicine, the draft rule would jeopardize the quality of care provided to patients who have obstructive sleep apnea (OSA), a serious medical disease that increases the risk of numerous health complications such as hypertension, cardiovascular disease and stroke. Dentists who follow the draft rule would be assuming the enormous risk of committing medical malpractice.

To protect the dental and medical professions, and to ensure the highest quality of care for patients, I urge the Colorado Medical Board to vigorously oppose this draft rule.

Sincerely,