

July 22, 2009

The Honorable Mike Ross
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Ross:

We wish to express our concerns regarding HR 3220, the Medicare Home Oxygen Therapy Act of 2009. Our organizations requested a meeting with your staff to discuss these concerns prior to the bill's introduction but unfortunately did not hear back in response to our meeting request. We now write to you to express our view that this legislation is fundamentally flawed – especially regarding adequate protection of patients and for clinical care.

Clinical Concerns

From the perspective of pulmonary physicians and respiratory therapists, there are several important issues raised by HR 3220. One overriding concern is that several provisions in the proposed legislation do not reflect the current science or technology of long term oxygen therapy (LTOT). HR 3220 proposes that patients are assigned to specific categories based on liter flow. This approach is flawed and contrary to existing science. Liter flow is a means to an end, with the clinical goal being the achievement of the appropriate blood oxygen saturation levels as determined by the prescribing physician. The clinical literature is definitive on this matter, and the standard of care for patients who require long term oxygen therapy is to ensure that patients are appropriately saturated; a liter flow as outlined in HR 3220 may or may not provide the individual with enough oxygen. Moreover, because of the technological advances made in nearly all portable devices using conserving technology, it is simply not possible to determine with any level of accuracy actual liter flow. Even if the technology existed to do so, it does not correlate to appropriate patient outcomes.

Section 3 of HR 3220 delineates “home oxygen therapy services.” To the pulmonary medicine community, **therapy services** by definition include provision of clinical services. In this specific case of LTOT, it involves administration of a drug (oxygen) by an FDA-approved device, with the goal of saturating the patient to levels identified by the prescribing physician, at rest and at exertion. Yet there is no mention of this clinical consideration at all. In discussions our groups have had with organizations such as CQRC and AAHomecare, they have consistently indicated that no clinical services are to be provided or authorized by the legislation. If that is indeed the case, the phrase “therapy services” is a misnomer and misleading as legislative provisions addressing comprehensive oxygen therapy are sadly lacking.

We are also troubled by the use of the term “provider” in the context of Medicare. While we fully recognize and appreciate the fact that oxygen providers do provide a range of important non-clinical services related to the delivery of oxygen equipment and supplies, the concept of “provider” puts these suppliers in a category similar to hospitals, nursing homes, home health agencies, hospices, etc. that are clearly recognized as providers of hands-on care. Inherent in the overall statutory concept of a Medicare “provider” is the provision of hands-on health care, and the definitive absence of clinical services seems to be contradictory. Additionally, as these “providers” must adhere to DME standards and DME accreditation and DME surety bond

requirements, we find the use of the term “provider” to be perhaps misleading. Also, HR 3220 defines delivery of specific clinical oxygen therapy services that should come under the scope of practice of formally trained and credentialed clinicians; however, there is no requirement to employ respiratory therapists, nurses or other health care professionals. Moreover, the legislation is ambiguous regarding whether the patient’s physician would be involved or if it would be the home oxygen company’s physician making many decisions.

Concerns Regarding Patient Safeguards

HR 3220 also fails to adequately protect patients and ensure that patients are afforded the proper safeguards. The legislation does not require home oxygen suppliers to accept all patients in need of oxygen, allowing the companies to pick the patients who are most economically lucrative to them or easiest to service. Moreover, HR 3220 also allows for the companies to terminate patients without just cause. None of these provisions are acceptable to our organizations.

We also believe the legislation could result in a significant decline in oxygen patients’ quality of life, particularly in regards to mobility. Since the new home oxygen regulations went into effect on January 1 of this year, our organizations have received dozens of calls and emails from patients whose home oxygen suppliers switched them to less expensive equipment that also significantly reduced the patients’ mobility and ability to lead an active and mobile life. While we generally accept HR 3220’s concept of three patient classification categories based on degree of ambulation, the determination of specific assignment to the category should be based on the prescribing physician’s clinical judgment of the approximate time, in average hours per day, that the physician estimates the patient is clinically able to ambulate AND, given a review of various lifestyle considerations, should be ambulating per day to ensure appropriate levels of health care. HR 3220 would codify the oxygen companies’ ability to pick devices, giving the home oxygen supplier the authority over the final selection of patient equipment – rather than the patient and his/her physician.

The language regarding the Home Oxygen Therapy Advisory Committee comes up short in a number of areas. First, it requires the Secretary to consult “with the home oxygen therapy community” – which allows the home oxygen industry to select the individuals and organizations they wish to see appointed to the Advisory Committee. Second, there is no defined number of participants – which could result in the committee representing only one point of view or being too large to be effective. The language also does not appear to require that a broad array of individuals and organizations be included on the Advisory Committee. Our organizations are concerned that this could leave patients and patient advocacy organizations out of this important committee.

We recognize that changes are needed to the current home oxygen payment and operating system, however, we cannot support the proposal laid out in HR 3220. We would welcome the opportunity to talk with you further about our concerns and work with you on a different proposal. Paul Billings, Vice President for National Policy and Advocacy with the American Lung Association, is happy to serve as the point of contact for our groups. He can be reached at 202-785-3355 or pbillings@lungusa.org.

Sincerely,

American College of Chest Physicians

American Lung Association

American Thoracic Society

National Association for Medical Direction of Respiratory Care

National Home Oxygen Patients Association

Cc: Chairman Henry Waxman, Committee on Energy and Commerce
Chairman Charlie Rangel, Committee on Ways and Means
Ranking Member Joe Barton, Committee on Energy and Commerce
Ranking Member Dave Camp, Committee on Ways and Means
Congressman Kendrick Meek