

Michigan Home Health Association

October 30, 2003

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, Maryland 20852

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Dear Colleagues:

The Michigan Home Health Association (MHHA) welcomes this opportunity to comment on the cGMP for Medical Gases draft guidance document. MHHA appreciates the research and expertise utilized for the development of these industry requirements. And, on whole, we agree with the proposed recommendations. In particular, we applaud the requirements regarding training, continuing education, testing and quality control.

However, we do wish to comment on areas which, in our estimation, pose a threat to the operations of home medical equipment providers. The issues we raise are of no concern to patient safety and quality of care! Our concerns are these:

- Calculation of Yield – reconciliation of product, which by nature is subject to evaporation and operating loss, will create an enormous paperwork burden to providers, without providing additional safety or value to patients.
- Inspection of labels, which have already been inspected for validity and approved for use, need not be performed by one person and independently verified by a second person. Quality control of labels removes the need for this second-person verification.
- Expiration dating requirements are unnecessary. Oxygen is a well-known element. Oxygen has been stored in steel and aluminum cylinders for many decades. It doesn't expire or become unstable. MHHA's recommendation would be to delete all requirements for stabilization testing and/or expiration dating.
- Verifying content pressures of cylinders stored for long periods in patients' homes would be tedious and burdensome for providers, again without any benefit for safety of patients. Patients and caregivers are given instruction on the safe use of these cylinders, including monitoring the content gauge.

The Michigan Home Health Association requests that you do not include the above proposed requirements in the final document because they would not affect the quality of care provided to home care patients. Your consideration is greatly appreciated.

Sincerely,

Harvey Zuckerberg
Executive Director

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