AMERICAN
ASSOCIATION
FOR
HOMECARE

Supporting Quality Health Care Services at Home

Via FedEx, and via fax (301) 827-6070

June 10, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0204
Bar Code Label Requirements for Human Drug Products and Blood

Dear Sir or Madam:

The American Association for Homecare (AAHomecare) provides the following comments as they relate to the proposed rule, "Bar Code Label Requirements for Human Drug Products and Blood", Docket 02N-0204, appearing in the Federal Register on March 14, 2003 at pages 12500 through 12534. In response to question 8 on page 12529 in the Federal Register notice, AAHomecare, proposes the agency exempt medical gases classified as drugs (as a class of products) from the proposed rule (21CFR §201.25 "Bar code label requirements").

AAHomecare represents 3,000 health care providers, manufacturers and suppliers who furnish home health services, rehab and assistive technologies, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to millions of Medicare and other government and private payors' beneficiaries. A significant percentage of our members provide medical gases to respiratory care patients at their residences. AAHomecare, therefore, limits its comments to medical gases classified as drugs.

In the Federal Register Notice for the proposed rule, the "Summary" (page 12500) states that bar coding will reduce medication errors, "by allowing healthcare professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time." As detailed in this letter, we believe medical gases warrant an exemption, given:

a) medical gases are uniquely packaged and used,
b) bar coding medical gases will not reduce the number of medication errors in the homecare setting, in hospitals, and other health care settings, and

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c) bar coding medical gases will not assist home healthcare professionals with assuring the aforementioned five "rights".

AAHomecare welcomes the opportunity to engage in further dialogue on this subject with the FDA.

Overview of Medical Gases Packaging and Their Use in Healthcare Settings

Most medical gases are classified as prescription drugs (i.e., Oxygen USP, Nitrogen NF, Medical Air USP, Nitrous Oxide USP, Carbon Dioxide USP, and Helium USP as well as some mixtures of these gases). In emergency situations and when administered by properly trained personnel, Oxygen USP may be administered without a prescription.

Medical gases, particularly oxygen, are administered in various settings. These settings include normal day to day environment where homecare patients self administer, institutional settings where ambulatory patients self administer (filling their own portable liquid units), and institutional settings where nurses and respiratory therapists administer medical gases.

Home respiratory care patients may obtain their oxygen via various modalities, including:

a) large stationary or small portable high-pressure cylinders,
b) stationary and portable liquid vessels (with proprietary connections), or
c) directly via oxygen concentrators (medical devices that do not require bar coding), or
d) indirectly via oxygen cylinders filled by concentrators designed to fill cylinders with Oxygen 93%, USP by patients in their homes. Neither the concentrator, nor the cylinder, would require a bar code under the proposed rule.

In hospitals, clinics or other institutional settings medical gases are typically administered via piping systems, supplied by bulk storage tanks, large cryogenic vessels, and/or high pressure cylinders, that are connected in remote areas, away from the pharmacy and patient use areas. Although homecare companies typically do not supply bulk oxygen into storage tanks, some companies may supply smaller institutions with large cryogenic vessels connected to a manifold and piped throughout the facility. The piping will end in the patient use area with a labeled and gas-specific wall outlet. Medical gases may also be administered in these environments via small (but still very large in comparison to unit dose packages) high-pressure cylinders or liquid containers. Medical gas container connections are also gas/gas property specific.

Physicians, dentists, and those involved in first aid/emergency care are also supplied with medical gases in labeled and color-coded high-pressure cylinders with gas-specific connections.

In contrast to typical pharmaceutical packages, produced by a limited number of manufacturers or repackagers with nationwide or regional distribution, medical gases are produced by a very large number of manufacturers/fillers, each with relatively limited geographical distribution. Due to the modality of the gas provided, and the patient-population served, medical gas manufacturers and

distributors often have significant overlap within limited geographical areas. An NDC labeler code search on the trade name "OXYGEN" yields well over a thousand NDC labeler codes, with a multitude of product and package codes. A similar search on "IBUPROFEN" yields less than 175 NDC labeler codes. Most medical gas manufacturers and private label distributors provide medical gases in two different modalities requiring two different NDC labeler codes for the same "gas" (due to differences in the safe handling and storage directions on the container label). For example, Oxygen USP may be provided in gaseous form in high pressure compressed gas cylinders with one label (and NDC code) and in cryogenic liquid form in cryogenic containers with a different label (and different NDC code) even though the Oxygen gas inhaled by the patient meets the same USP specifications. AAHomecare questions the ability for hospitals and other health care entities to maintain a database that may require multiple thousands of NDC labeler and product code combinations just for medical gases and the software that will allow several NDC codes (that include company, product, and package code information) to be "scanned" for the same drug.

Home healthcare firms that provide Oxygen to patients at their residences would fall under this proposed rule, as they are not exempt from the establishment registration and listing requirements (per section 510(g)(1) of the Act). Filling liquid oxygen containers at a patient's residence, even though conducted in a retail capacity, is considered a "manufacturing" activity. The rationale provided by the agency for omitting prescription drug samples from the proposed bar code requirement, "because patients would not have or be inclined to buy bar code scanners for their own use in the immediate future", should also apply to oxygen supplied to patients at their residence. Patients utilizing an oxygen concentrator (a device not requiring bar code) in their home, utilize high-pressure cylinders (drug product containers subject to the proposed rule) as their back-up source in case of power failure. Even though the oxygen strength differs between the output of a concentrator and that provided in the cylinder, the gases are therapeutically equivalent. One product would require a bar code and the other would not. Bar coding medical gases will not assist in preventing medication errors in the home as further discussed below with respect to the five "rights".

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Drug" Right

Bar coding drug medical gas package labels (high pressure cylinders or cryogenic vessels) is unlikely to prevent "wrong drug" medication errors. When the relatively few medical gas mix-ups have occurred at healthcare facilities, existing safety systems were compromised. Either the medical gas manufacturer or the person installing the container on the utilization or distribution equipment, compromised the safety systems by removing, changing, or modifying the gas property-specific connection(s) on the gas container or gas utilization equipment, or by using cross product adapters. Current regulations and regulatory initiatives address the issues that have resulted in medical gas mix-ups.

Medical oxygen, in almost all instances, is the only medical gas prescribed for use in the home, therefore no other medical gases are available to the patient. Even if a patient had more than one

medical gas (and had a scanner) the inherent safety systems (different label, connection, and color code) would need to be circumvented in order to have a mix-up at the patient's home.

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Dose" Right

While bar coding unit dose packaging may assist with the "right dose" aspect of many traditional pharmaceuticals, medical gases are not produced in unit dose packages nor can the labeling indicate the number of "doses" therein contained. Bar coding labels on medical gas containers would therefore not assist with the "right dose" right for medical gases. High-pressure cylinders contain from less than one hundred up to several thousand liters of gas. Liquid containers are capable of holding significantly more (hundreds of thousands). Container size or net contents have no bearing on dose. "Doses" prescribed by a physician for a patient in a healthcare facility, or at a patient's residence, are controlled by a pressure-regulator/gas flow meter (medical device), typically providing from less than 1 liter per minute to up to 10 liters per minute. A physician would not prescribe "one cylinder" of oxygen. Rather a physician would prescribe a specific flow rate for a specific duration of time (e.g., 2 liters/minute for 24 hours per day).

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Patient" Right

Unlike in institutional settings, homecare services are provided at the patient's home where computers would not be readily available to immediately confirm the patient's identity via bar code. Homecare patients do not wear identification wristbands that are commonly found in the acute and sub-acute care setting. However, there currently are patient-identifiers inherent to the homecare setting that assure "right patient" such as, a delivery ticket that would include a unique address and patient identification number, and provider familiarity with the homecare patient.

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Route of Administration" Right

Aside from the use of some cryogenic liquids in surgical applications and lab use (where again the containers utilize unique fittings to prevent mix-ups), medical gases have only one route of administration – inhalation. Basic training of medical staff and education of homecare patients assure medical gases are administered via the proper route of administration. Medical gases are administered by inhalation via nasal cannula, mask, endotracheal or tracheostomy tube. It is unnecessary to rely on a bar-coded label on a cylinder or container to assure the medical gases "right route of administration".

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Time" Right

Unlike traditional pharmaceuticals dispensed at certain intervals, "right time" medication administration errors (e.g., failing to provide the drug at the right time or providing it at multiple

times) do not apply to medical gases. Medical oxygen in the home care setting is used for the duration prescribed by the physician (e.g., 24 hours per day, nocturnal, during exercise, etc.).

From our review of the studies cited in the Federal Register notice, it is evident that medical gases were not included in the medication error data (perhaps because there have been very few medical gas medication errors when compared to other pharmaceutical medication errors). It also appears medical gases were not included in the economic impact data presented. Based on discussions with agency personnel, our understanding is that over fifty percent of all drug manufacturers registered with the agency are medical gas firms, and many of those would be classified as small business. The financial impact of this rule on these firms as well as larger regional and nationwide firms would be very significant if an exemption for this class of products is not granted. Contrary to the overall goal of trying to stem the increased cost of healthcare in the United States, this rule will significantly add cost to the manufacture, distribution, and even users (healthcare institutions and patients) of medical gases with minimal, or no, benefit.

AAHomecare firmly believes the arguments it has put forth provide adequate rationale for the agency to exempt medical gases from the requirements of proposed 21 CFR 201.25. If the agency does not concur with our request to exempt medical gases from the rule, we strongly recommend that prior to publishing this as a final rule, the agency meet with the American Association for Homecare. The purpose of a meeting would be to discuss the degree this regulation will impact this industry and more importantly further discuss the minimal potential health benefit, if any, that this regulation will have on the administration of medical gases.

AAHomecare appreciates the opportunity to comment on this proposed rule. If there are any questions regarding the request for exemption, please do not hesitate to contact Kay Cox, President, AAHomecare, via e-mail at kayc@aahomecare.com, or via phone at (703) 836-6263. We will contact you on June 11, 2003 to verify your receipt of this letter and to discuss when a meeting, if necessary, could be scheduled. Thank you for your consideration.

Sincerely,

Kay Cox

Kay Cox
President and Chief Executive Officer
American Association for Homecare