APRIA HEALTHCARE®

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Food and Drug Administration
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Sent via FedEx overnight
Faxed on 6/12/03 to 301/827-6880

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

Dear Sir or Madam:

Apria Healthcare 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").

Apria Healthcare provides home healthcare products and services, including medical oxygen, respiratory equipment, and a broad range of medical supplies and equipment. With approximately 410 locations nationwide, Apria serves over 1.3 million patients annually throughout all 50 states. As a manufacture of a single medical gas (Oxygen USP), Apria limits its comments to this medical gas classified as a drug.

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 oxygen warrants an exemption, given:\

a) medical oxygen is uniquely packaged and used,
b) bar coding medical oxygen will not reduce the number of medication errors in the homecare setting, and
c) bar coding medical oxygen will not assist home healthcare professionals with assuring the aforementioned five "rights".

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Overview of Medical Oxygen Packaging and Use in The Homecare Setting

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 medical oxygen, are administered in various settings. These settings include normal day to day environs 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 medical 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 institutional settings medical oxygen is 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 of medical oxygen 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 oxygen 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.

In contrast to typical pharmaceutical packages, produced by a limited number of manufacturers or repackagers with nationwide or regional distribution, medical oxygen is 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 oxygen 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. Apria Healthcare questions the ability for hospitals and other health care entities to maintain a database that may require thousands of NDC labeler and product code combinations just for medical oxygen provided by manufacturers to their facility, 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 medical 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. 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 oxygen is not produced in unit dose packages nor can the labeling indicate the number of "doses" therein contained. Bar coding labels on medical oxygen 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) liters. Container size or net contents have no bearing on dose. "Dosage" prescribed by a physician for

a patient in the home setting , is 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. In addition, because patients are typically on long-term oxygen therapy, providers can rely on visual identity of the homecare patient coupled with the other unique identifiers.

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

Medical oxygen has only one route of administration – inhalation in the homecare setting. Basic training of medical staff and education of homecare patients assure medical oxygen is administered via the proper route of administration. Medical oxygen is 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" in the homecare setting.

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 oxygen. 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 oxygen was not included in the medication error data (perhaps because there have been very few medical oxygen medication errors when compared to other pharmaceutical medication errors). It also appears medical oxygen was 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.

Apria Healthcare firmly believes the arguments it has put forth provide adequate rationale for the agency to exempt medical oxygen 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 such a meeting would be to discuss the degree this regulation will impact the homecare industry; and more importantly further discuss the minimal potential health benefit, if any, that this regulation will have on the reduction of medication errors associated with the administration of medical oxygen in the homecare setting.

Apria Healthcare 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 me via phone at (949) 639-2000. Thank you for your consideration in this very important issue.

Sincerely,

Lawrence M. Higby
President and Chief Executive Officer
Apria Healthcare