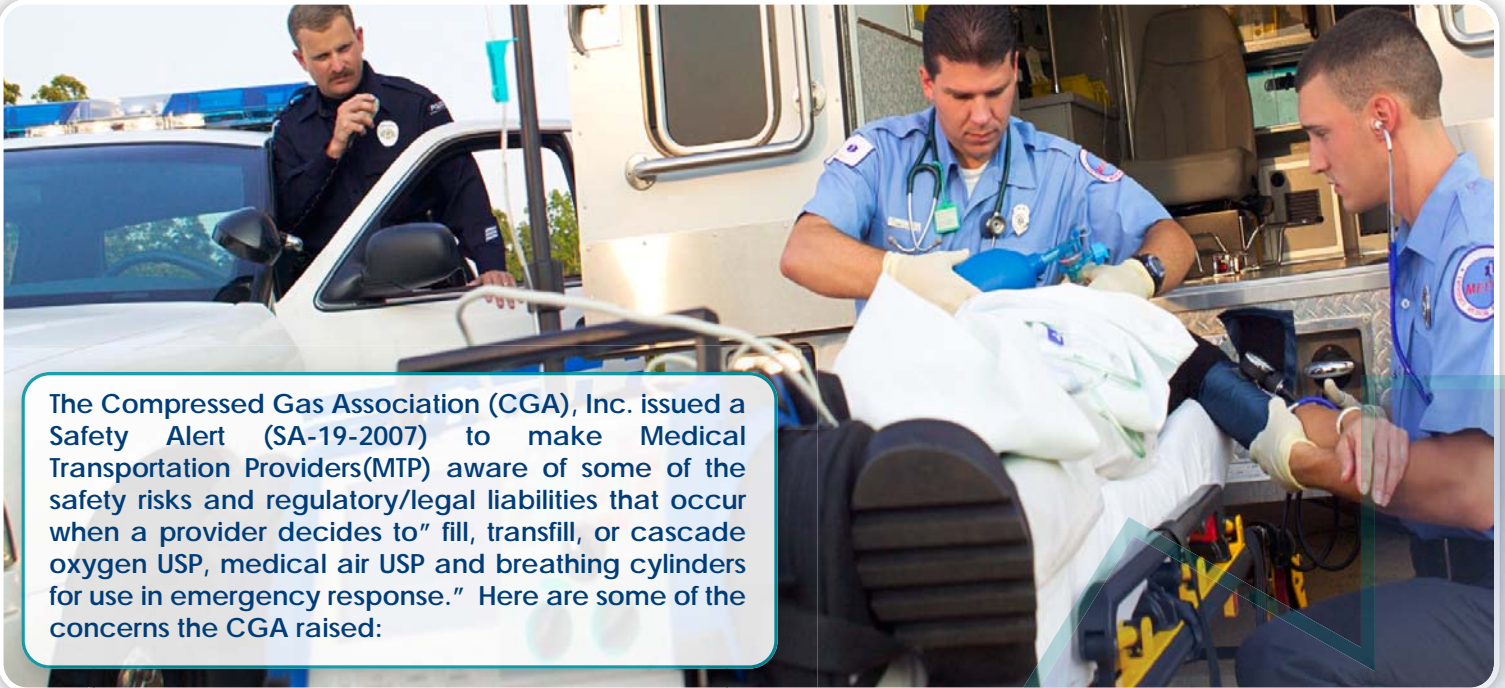




Filling of Medical Gases by Emergency Medical Services



The Compressed Gas Association (CGA), Inc. issued a Safety Alert (SA-19-2007) to make Medical Transportation Providers (MTP) aware of some of the safety risks and regulatory/legal liabilities that occur when a provider decides to "fill, transfill, or cascade oxygen USP, medical air USP and breathing cylinders for use in emergency response." Here are some of the concerns the CGA raised:

- Accidents that resulted in injury and death have occurred when the quality and integrity of the gas filling equipment were not sufficient to address material compatibility, component pressure ratings, safety relief devices, pressure gauges, cleaning processes and the like.
- Only trained, qualified personnel, who are familiar with the transfilling procedure, equipment and precautions necessary to comply with all pertinent regulations, should perform transfilling of high pressure compressed gas cylinders. See CGA P-2.5 Transfilling of High Pressure Gaseous Oxygen To Be Used for Respiration.
- The US Department of Transportation (DOT) has requirements defined in Title 49 of the US Code of Federal Regulations, Part 173.301(e) that make it mandatory that fillers of DOT cylinders have the written permission of the cylinder owner, before they fill them. If you fill a cylinder you don't own and don't have permission in writing, you are in violation of this DOT regulation.
- The DOT has specific periodic retest and inspection criteria. The DOT and FDA have recordkeeping requirements for the inspection, testing and filling of cylinders. The scope of transfilling activities could make the MTP fit the FDA definition of manufacturer. They would then be required to register with the FDA, list their products and comply with Good Manufacturing Practices (GMP) per 21 CFR, Parts 201, 205, 210, and 211.
- GMP requires a specific, written SOP that defines prefill inspection, filling, postfill inspection, testing, labeling, holding and distributions of medical gases.
- 21 CFR 201 specifies product labeling requirements. MTPs can't refill cylinders when they have a product label that identifies another entity as the filler. See CGA C-7, Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers.

This is a partial list. There are federal, state, and local regulations. Find more information at www.cganet.com and www.gpoaccess.gov. "Fires Involving Medical Oxygen Equipment" is available at: www.usfa.fema.gov/downloads/pdf/publications/tr-107.pdf.