



COVID-19 AND THE SUPPLY OF PPE: COBB COUNTY ALLOWS STERIGENICS TO TEMPORARILY RESUME OPERATIONS

On March 25, 2020, Cobb County, Georgia issued an order authorizing the Sterigenics commercial sterilization facility to temporarily resume operations in order to sterilize personal protective equipment (PPE) “necessary to stem and combat the spread of the current global COVID-19 pandemic.”¹ I had written about the controversy surrounding this facility in an earlier article that focused on the availability and use of emergency shutdown orders by regulatory authorities. This facility had been the focus of scrutiny by regulators following news reports raising concerns about its use of ethylene oxide in the sterilization process. I had noted that among the other regulatory actions taken, Cobb County’s fire marshal had ordered the facility to remain closed pending completion of a review of its compliance with applicable fire safety standards. This order was still in place prior to the issuance of the Emergency Authorization.

The County characterizes the relief it granted as a “limited emergency authorization.” As grounds for its authority to issue the Emergency Authorization, the County pointed to the Declaration of Emergency it had issued in response to the COVID-19 pandemic on March 24, 2020, and cited provisions in the County’s Official Code allowing the County Manager to suspend code provisions if necessary to “[p]revent, hinder or delay necessary action in coping with ... [an] emergency.” In addition to limiting Sterigenics’ operations to sterilization of PPE necessary to stem the tide of the COVID-19 pandemic, the Emergency Authorization also, among other things: (i) restricts the amount of ethylene oxide that can be stored in the facility’s ethylene oxide storage and chamber room areas; (ii) requires Sterigenics to “[t]ake swift action to address the outstanding permit issues at the [f]acility...”; and (iii) requires that any spills, leaks or “other life-threatening incident” be reported to Georgia EPD and the Cobb County Manager within one hour.

This action was taken in response to communications from the U.S. Food and Drug Administration expressing concern that the need for PPE, such as protective masks, may outpace the supply available to healthcare organizations on the front lines of the fight against the ongoing pandemic.² To this point, at the time of the issuance of the Emergency Authorization,

¹ *Order Pursuant to Declaration of Emergency in Cobb County Permitting Temporary Resumption of Operations by Sterigenics for the Sterilization of Personal Protective Equipment (PPE) Necessary to Combat the COVID-19 Pandemic* (Cobb County Bd. Of Comm’rs March 25, 2020)(referred to herein as the “Emergency Authorization”).

² Emergency Order, p. 1; see also Letter from Stephen M. Hahn, M.D., Commissioner of Food and Drugs to The Honorable Brian P. Kemp, Governor of the State of Georgia (March 19, 2020).



approximately 200 truckloads of PPE were at the Sterigenics facility awaiting sterilization. Presumably, the County's action will ease some of the supply constraints that currently have public health officials worried. However, as the Emergency Authorization makes clear, this action was in response to, and only addresses, concerns related to PPE. In the meantime, Sterigenics has raised concerns about its ability to sterilize other types of medical equipment, such as ventilator tubing, that are also necessary in the fight against the COVID-19 pandemic.³

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³ Klepal, Dan, *Sterigenics: Cobb's Order Allowing It to Re-open Fails to Protect Public*, The Atlanta Journal-Constitution, March 26, 2020. <https://www.ajc.com/news/local-govt--politics/sterigenics-cobb-order-allowing-reopen-fails-protect-public/nDo6AxiUvaZoeAu5Std7ZN/>