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Examining the Drug Supply Chain – How the Public Health Emergency Impacts DSCSA

by Brendan Carroll

On April 30, 2020, the U.S. Food and Drug Administration (FDA) issued new guidance, "Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency," to clarify how provisions of the Drug Supply Chain Security Act (DSCSA) may affect the prescription drug supply chain during the COVID-19 pandemic. When Secretary of Health and Human Services Alex M. Azar declared a public health emergency under Section 319 of the Public Health Service Act, he triggered provisions of the DSCSA that automatically exclude certain activities from the DSCSA definitions of "transaction" and "wholesale distribution." It is worth noting that the authority being discussed in the FDA's guidance is neither new nor different from what has existed for many years. In fact, public health emergencies and DSCSA requirements were a featured page on the FDA's website and included in a November 15, 2017 FDA presentation by the deputy director of the Office of Compliance (FDA/CDER) on the Drug Supply Chain Security Act.

"Emergency Medical Reasons" Under the DSCSA

The distribution of pharmaceutical products for "emergency medical reasons" is expressly contemplated in two definitions under the DSCSA. In the guidance, the FDA clarifies that these automatically triggered statutory provisions operate to *exempt* certain product distribution activities from the DSCSA definition of "transaction" under Section 581(24) and to *exclude* certain product distribution activities from the definition of "wholesale distribution" under the Federal Food, Drug, and Cosmetic Act (FDCA).

The semantics of the terms "exemption" or "exclusion" are secondary to the FDA's interpretation of the types of product distribution activities this statutory exemption and exclusion apply to. During the COVID-19 public health emergency, the FDA states that these requirements apply very narrowly to "covered COVID-19 products" and, a bit more broadly, to certain distribution activities that are directly impacted by the COVID-19 pandemic and meet emergency medical needs – in other words, to other, noncovered COVID-19-affected products.

Why is the first application so narrow? Well, the FDA interprets covered COVID-19 products to include prescription drug products either (1) issued an emergency use authorization (EUA) under Section 564 of the FDCA to combat COVID-19; or (2) approved by the FDA to diagnose, cure, mitigate, treat, or prevent COVID-19. There are no products approved for the latter, and only chloroquine phosphate, hydroxychloroquine sulfate, and remdesivir are currently subject to an EUA.

So what about other affected products? The guidance states that the distribution of other products affected by the COVID-19 public health emergency includes circumstances when an entity is engaging in distribution activities that are:

- For emergency medical reasons, including the treatment of COVID-19 symptoms.
- Directly impacted by COVID-19.

When determining whether distribution activities are directly impacted by COVID-19, the FDA cites examples of geographic limitations (either due to limited local supply or high demand), impacts to operating capabilities (necessitating a need for a new, temporary facility), and dispenser-to-dispenser transactions.

Enforcement Discretion

Unlike many of the FDA's guidance documents that have been published since the announcement of the public health emergency, this guidance does not announce a broad enforcement policy that otherwise permits authorized (or unauthorized) trading partners to circumvent key requirements of the DSCSA. However, in Section III.D of the guidance, the FDA does state that it does not intend to take enforcement action against trading partners engaged in two types of activities.

First, the FDA will not take enforcement action against entities that would otherwise meet the definition of "wholesale distributor," as a result of the exclusion from the definition of "wholesale distribution" for emergency reasons. Don't be fooled – this is not an exercise of enforcement discretion; rather, this is merely the outcome of one of the automatically triggered statutory provisions. Such activities are excluded by law, not by this guidance.

Second, the FDA will not take enforcement action against distributions involving other trading partners that are not authorized "solely because of circumstances directly related to the COVID-19 public health emergency," but are working with, or have been permitted by state authorities, to operate during the COVID-19 pandemic. Under Section 581(2), the term "authorized" generally refers to having a valid registration (manufacturer or repackager) or having a valid license under state law and complying with licensure reporting requirements (wholesale distributor and third-party logistics providers (3PLs)).

Although this more accurately represents exercise of FDA enforcement discretion, such licensure requirements nonetheless extend beyond federal requirements under the DSCSA and implicate state requirements. While the FDA states it will not take enforcement action, state authorities may have the final say.

What About State Authorities?

It is important to distinguish between federal DSCSA requirements and separate state requirements. The FDA clearly states the following:

> We do not interpret the exclusion from wholesale distribution for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the PHS Act, to affect the ability of States to require licensure of such entities as wholesale distributors under State law.

This is significant because in 2013, the DSCSA had the effect of preempting state law. The DSCSA contained two preemption provisions, one regarding track and trace, and the other regarding wholesale distributor and 3PL licensure and standards. There have been many open questions about the scope of DSCSA preemption for wholesale distributors and 3PLs over the years, but the issues have never been fully resolved. In fact, in a February 2018 speech, then-FDA Commissioner Scott Gottlieb acknowledged confusion over the scope of licensure preemption and announced that the FDA would update its preemption interpretation under the 2014 draft guidance. To date, the FDA has taken no such action.

In other words, states had to change their laws after 2013 to remove obsolete requirements preempted by the DSCSA but still have variable, evolving, and often confusing state licensure laws in place. Requirements for wholesale distributors and 3PLs continue to change across various states. For this reason, the FDA statements in this guidance expressly do not affect the ability of states to continue to require licensure as wholesale distributors under state law – whether or not COVID-19 impacts this activity.

State boards of pharmacy (or equivalent state health authorities) – separate and apart from this guidance – have been making determinations about whether additional enforcement discretion may be warranted. For example, Nevada has established a process to request certain regulatory waivers from the board. Ohio has issued a resolution for licensure requirements during a public health emergency, finding that it is in the public's interest to waive drug distributor licensure requirements during this time. Still other states have relied upon their own enforcement discretion.

While the FDA may exercise enforcement, it is important to confirm that the applicable state will, too.

A Look Ahead

As the United States grapples with ongoing supply chain issues, the DCSCA presents some critical protections, while highlighting some unique challenges. One of the key purposes of the enactment of the DCSCA was to protect consumers from exposure to drugs that may be counterfeit or otherwise harmful. This is more important than ever, as the FDA continues to issue countless warning letters to companies flooding the market with illegal, adulterated and misbranded, and counterfeit products.

At the same time, the impact of COVID-19 on the supply chain has been devastating. Now the very requirements put in place to address vulnerabilities in the drug supply chain and protect consumers may be a factor in creating further supply chain issues. Drug shortages remain an obvious concern, and the list continues to grow. Interestingly, the definition of wholesale distribution even states that "a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason" – but might that just be a distinction without a difference?

Alston & Bird has formed a multidisciplinary task force to advise clients on the business and legal implications of the coronavirus (COVID-19). You can view all our work on the coronavirus across industries and subscribe to our future webinars and advisories.

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