

CORONAVIRUS INFORMATION & UPDATES

April 9, 2020

FEMA to Impose COVID-19-Related Export Restrictions on Medical Equipment

On April 7, 2020, the Federal Emergency Management Agency (“FEMA”), within the U.S. Department of Homeland Security (“DHS”), issued a temporary rule (the “Rule”) that proposes to restrict companies from exporting from the United States certain medical supplies, including respirators and gloves, absent governmental authorization. Intended to help ensure an adequate domestic supply of equipment needed to confront the novel coronavirus (“COVID-19”), the Rule will create operational challenges for life sciences and medical device companies that export covered products.

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Background

Over the last several weeks, the Trump administration has issued various Executive Orders and related memoranda aimed at expanding the capability of the federal government to confront COVID-19. Although these actions are based on the President’s expansive authority under the Defense Production Act of 1950, their scope has been relatively limited to date.¹

On April 3, 2020, President Trump issued a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (the “Memorandum”), directing the Secretary of Homeland Security, in consultation with the Department of Health and Human Services (“HHS”), to take all available steps to allocate to domestic use certain covered materials. The Memorandum states, in pertinent part, that “it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries from diverting such material overseas.”²

The Rule

Pursuant to the Memorandum, on April 7, FEMA issued the Rule to allocate certain scarce or threatened materials to domestic use.³ The Rule will become effective on April 10 when published in the Federal Register, and is currently scheduled to be in effect for 120 days (*i.e.*, until August 8, 2020).

The Rule covers the following categories of “covered materials,” which are consistent with the product categories described in the Memorandum:⁴

- N-95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;
- Other Filtering Facepiece Respirators, including single-use, disposable half-mask respirator protective devices that cover the user’s airway (nose and mouth) and offer protection from particulate materials at or above an N95 filtration efficiency level, per 42 C.F.R. § 84.181 (*e.g.*, those designated as N99, N100, R95, R99, R100, P95, P99, or P100);
- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;

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- PPE [personal protective equipment] surgical masks, including masks that cover the user’s nose and mouth and provide a physical barrier to fluids and particulate materials; and
- PPE gloves or surgical gloves, including those defined at 21 C.F.R. §§ 880.6250 (exam gloves) and 878.4460 (surgical gloves), and other gloves intended for the same purpose.

The Rule contemplates that, when a party seeks to export covered materials, U.S. Customs and Border Protection (“CBP”), in coordination with other agencies as appropriate, will notify FEMA. CBP will temporarily detain the shipment, until FEMA determines whether to (1) return the products for domestic use; (2) issue a rated order for part or all of the shipment; or (3) allow the shipment to proceed.

The Rule provides that, in making this determination, FEMA “will consider the totality of the circumstances,” including (1) the need to ensure that scarce or threatened items are appropriately allocated for domestic use; (2) minimization of disruption to the supply chain, both domestically and abroad; (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns; (4) the quantity and quality of the materials; (5) humanitarian considerations; and (6) international relations and diplomatic considerations.⁵

Key Takeaways

1. **The Rule applies to all exporters.** In contrast to earlier executive actions, the Rule will apply to **all** exporters and all exports of covered materials from the United States. Accordingly, **all** companies that export covered materials from the United States must assess whether the Rule will restrict export activities that, prior to the COVID-19 pandemic, constituted ordinary course business.
2. **The Rule does not provide for pre-export consultation with FEMA.** The Rule states that covered materials “may not be exported from the United States without explicit approval by FEMA.” However, the Rule does not set out a procedure for consulting with FEMA, in advance of initiating an export transaction, to determine whether the transaction will be permitted to move forward.⁶ Until further guidance or clarification is issued, the Rule appears to require prospective exporters to initiate a transaction as they normally would, knowing the transaction will be detained by CBP and then delayed as FEMA conducts a review.
3. **The Rule’s implementation will depend upon the practices of individual CBP ports.** While FEMA has the ultimate authority to determine whether covered materials may be exported, CBP is required, in the first instance, to identify shipments of covered materials and to “temporarily detain any shipment of such covered materials, pending [FEMA’s] determination[.]”⁷ CBP operates at hundreds of ports throughout the United States, and each individual port has different staff and individual port practices. Certain ports may prove more vigilant in screening shipments and halting exports than others. Accordingly, in practice, geographic factors may dictate which companies are most affected by the Rule.
4. **The Rule provides significant discretion to FEMA.** The Rule gives FEMA significant authority to determine, on a case-by-case basis, whether an export transaction can proceed. The only exemption incorporated in the Rule⁸ is for exports by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, *provided that* at least 80% of such manufacturer’s domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months.⁹ Even if an exporter is

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able to meet this exemption, FEMA has the authority to “waive [the] exemption . . . if the Administrator determines that doing so is necessary or appropriate to promote the national defense.”¹⁰ Furthermore, the Rule “encourages manufacturers to contact FEMA with specific information regarding their status under this exemption,” suggesting that immediate application of the exemption in a given transaction may be unlikely.¹¹

5. **The Rule may significantly disrupt supply chains or cause companies to rethink their shipping practices, at least in the short term.** Although the Rule states that FEMA “will make [its] determination within a reasonable timeframe after notification of an intended export,” delays are foreseeable.¹² Companies that export covered materials may be required to weigh the benefits of continued activity against the reality that future exports will be delayed (and that certain exports will be disallowed). In addition, companies with the flexibility to do so may consider shifting manufacturing outside the United States, or reordering shipping routes to avoid the delays and uncertainty created by the Rule.
6. **Further guidance may be required.** Already, the Memorandum and the Rule have sparked extensive questions and concerns among life sciences and medical device companies. Many companies already have contacted FEMA and CBP to seek further guidance, including with respect to (1) whether FEMA intends to offer a pre-consultation process; (2) how FEMA and CBP will administer the screening process; and (3) the legality of pending and future export transactions. Given the widespread effects of the Rule, it is foreseeable that the U.S. government will feel compelled to provide further guidance to the export community (particularly if the COVID-19 pandemic continues to develop, necessitating further changes).
 1. For example, a March 27 memorandum instructed the U.S. Department of Health and Human Services (“HHS”) to take steps to ensure that General Motors Company would accept, perform, and prioritize orders for ventilators. Similarly, an April 2 memorandum directed DHS to acquire as many N-95 respirators from 3M Company as possible.
 2. White House, Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (Apr. 3, 2020), available at <https://www.whitehouse.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/>.
 3. Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use (Apr. 7, 2020), available at <https://www.federalregister.gov/documents/2020/04/10/2020-07659/prioritization-and-allocation-of-certain-scarce-or-threatened-health-and-medical-resources-for->.
 4. *Id.* at 21-22. FEMA has the authority to designate additional equipment and materials to be subject to the allocation order. *Id.* at 12.
 5. *Id.* at 20.
 6. *Id.* at 19.
 7. *Id.*
 8. The Rule states that FEMA “may establish . . . additional exemptions that . . . are necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the *Federal Register*.” *Id.* at 11.
 9. *Id.* at 20.
 10. *Id.*
 11. *Id.* at 11.
 12. *Id.* at 19.