

## Federal Protections Against Liability For Businesses Combatting COVID-19

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### Key Points

- Federal emergency authorities targeting COVID-19 provide important protections to businesses for certain actions in connection with the national response to the public health crisis.
- The protections include immunity from tort, contract and antitrust liability, and waiver of sanctions for certain physician self-referrals.
- Future legislation and other government action may create additional protections.

Federal emergency authorities activated to aid in combatting the COVID-19 pandemic incorporate important protections for the businesses and individuals who are part of the nation's response to the current public health emergency. The protections include immunities from tort liability, antitrust liability and contract liability for actions like manufacture of products to diagnose and treat COVID-19, supply of those products and the materials used to make them, volunteering professional health care services and sanctions for certain physician self-referrals.

Specifically, Secretary of Health and Human Services (HHS) Alex Azar's declaration of a public health emergency under the Public Readiness and Emergency Preparedness (PREP) Act activated that Act's immunities. President Trump's invocation of the Defense Production Act (DPA) makes available immunities for actions based on the DPA. The Coronavirus Aid, Relief and Economic Security (CARES) Act stimulus package broadens the scope of immunity under the PREP Act as well as grants protection to health care professionals volunteering care. HHS has invoked its waiver authority under the Federal Physician Self-Referral Law (the "Stark Law") to allow certain physician self-referral arrangements that ordinarily would be subject to sanctions. And, relatedly, the HHS Office of Inspector General (OIG) has stated that it will not seek administrative sanctions under the Anti-Kickback Statute based on the allowed arrangements.

This article describes each of these authorities and how its protections apply during the COVID-19 emergency. It concludes by recognizing the possibility of additional

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protections as the federal and state governments continue to address to the public health crisis.

## Public Readiness and Emergency Preparedness Act

The PREP Act provides limited immunity for businesses and individuals that develop, test, manufacture, distribute, administer, prescribe or use “covered countermeasures” in combatting a public health emergency. 42 U.S.C. § 247d–6d. These businesses and persons are protected from liability under federal and state law for all claims, including tort liability, arising out of, relating to or resulting from covered countermeasures, except in cases of willful misconduct.

As applicable to the COVID-19 public health emergency declared by Secretary Azar on March 17, covered countermeasures include antivirals, drugs, biologics and vaccines used to diagnose and treat the coronavirus. Devices used in responding to COVID-19, ventilators for example, also are covered countermeasures. The CARES Act amended the PREP Act to add respiratory protective devices (masks) as another covered countermeasure. CARES Act § 3103. Secretary Azar’s March 17 declaration limits PREP Act immunity to covered countermeasures that are encompassed by certain federal, state or local governmental authorizations.

Secretary Azar’s declaration of public health emergency triggering PREP Act immunity is retroactive to February 4, 2020, and extends to October 1, 2024.

## Defense Production Act

The President’s March 18 Executive Order invoking the DPA found that “health and medical resources needed to respond to the spread of COVID-19, including personal protective equipment and ventilators” are critical and warrant activation of the Act’s powers to control production and supply of critical materials. In addition to the powers the DPA affords the President, the Act provides private industry with specified protections:

### **Protection against liability resulting from compliance with DPA orders**

The DPA immunizes businesses and individuals from damages and penalties for actions in compliance with an order, regulation or rule issued pursuant to that Act, regardless of whether the direction is later deemed invalid. 50 U.S.C. § 4557. During the current COVID-19 emergency, the President has invoked the DPA three times, each time by authorizing the HHS Secretary and/or the Department of Homeland Security (DHS) Secretary to issue orders to medical equipment and supply manufacturers. The President authorized the issuance of orders to: (1) General Motors (GM) regarding production of ventilators; (2) manufacturers and suppliers of materials utilized in producing ventilators; and (3) 3M regarding production and distribution of N95 respirators (masks).

If the HHS or DHS directs one of these businesses to take specific action, for example, a direction to GM to fill the government’s orders for ventilators ahead of other customers’ pre-existing orders, the business is protected from a claim for damages or penalties stemming from that action. Any business compelled under the DPA to produce or otherwise provide health or medical resources would similarly enjoy immunity for its actions to comply. Importantly, however, this DPA immunity has been interpreted as limited to liability stemming from the risks the Act creates, principally

interference with pre-existing contracts, and not to extend to other liability such as product liability. E.g., *Hercules Inc. v. United States*, 24 F.3d 188, 203 (Fed. Cir. 1994), *aff'd*, 516 U.S. 417 (1996).

### **Protection against contract liability for actions under voluntary agreements with the government**

Until the HHS or DHS actually issues an order directing a business to take specific action, presidential orders under the DPA can be viewed as serving primarily to pressure businesses to negotiate with the government to provide the needed health or medical resources. Indeed, shortly after the President's order authorizing the DHS Secretary to compel 3M to provide N95 masks for use in the United States, 3M reached a deal with the White House on the masks.

To encourage and support voluntary agreements between private industry and the government, the DPA provides a defense, available in both federal and state court, to claims for breach of contract that applies where an alleged breach was "predominantly" caused by action under a voluntary agreement authorized by the DPA. 50 U.S.C. § 4558(o). Customers with pre-existing contracts or orders that are delayed or disrupted because of voluntary agreements authorized by the DPA cannot sue for breach of contract. Businesses should note, however, that they must still mitigate damages, as required under applicable law, "to the greatest extent possible." It is also important to note that even in the case of a breach-of-contract action by a commercial customer against a provider to the government, the DPA does not require that the government hold the company harmless from or provide indemnification for the cost of defending against such breach-of-contract action.

### **Antitrust immunity**

The DPA also provides limited antitrust immunity for actions taken under a voluntary agreement or plan of action authorized by the Act. 50 U.S.C. § 4558(j). The Act creates a defense to any civil or criminal action brought under federal or state antitrust law for any act taken to carry out an authorized voluntary agreement or plan of action. For antitrust immunity to apply, the voluntary agreement or plan must be actively supervised by the President or his designee. Immunity is not available for actions taken for the purpose of violating antitrust laws.

Consistent with the DPA's intent to prevent application of antitrust principles that ordinarily preclude collaboration by competitors, the U.S. Department of Justice (DOJ) recently announced its intention not to challenge the joint effort of five medical supply companies to expedite manufacture and delivery of personal protective equipment and medication to treat COVID-19.

### **CARES Act Immunity for Volunteering Health Care Professionals**

In addition to broadening the countermeasures covered by PREP Act immunity as described above, the CARES Act limits liability of health care professionals who voluntarily provide care to COVID-19 patients during the present public health emergency. CARES Act § 3215. Volunteering health care professionals cannot be liable under federal or state law for any harm from their provision of health care services relating to COVID-19 during this time. This immunity extends only to volunteered services provided in good faith and within the scope of the volunteer's professional license, registration or certification. It does not cover willful, criminal or

reckless misconduct, gross negligence, flagrant indifference or actions under the influence of alcohol or an intoxicating drug.

Although the focus of this article is federal protections against liability, it is noteworthy that several states have enacted immunity provisions that are similar to the CARES Act provision but cover all health care providers and health care facilities, not just volunteers.

### **Waiver of Certain Sanctions under the Stark Law and Anti-Kickback Statute**

The Stark Law generally prohibits a physician from making referrals for Medicare-payable services to an entity with which the physician or an immediate family member has a financial relationship, under penalty of sanctions. 42 U.S.C. § 1395nn. The law authorizes the HHS Secretary to temporarily waive sanctions where the President has declared an emergency and the Secretary has declared a public health emergency. 42 U.S.C. § 1320b-5(b)(4). On March 30, Secretary Azar utilized his waiver authority to issue blanket waivers from sanctions under the Stark Law for certain referrals, remuneration and other conduct in the course of responding to COVID-19, provided the conduct meets specified criteria and does not implicate fraud or abuse. The waivers are retroactive to March 1, 2020, and effective during the length of the COVID-19 public health emergency.

Relatedly, the HHS OIG announced on April 3 that it will exercise its discretion not to seek administrative sanctions under the Anti-Kickback Statute for remunerations on or after April 3 that meet the criteria of the Secretary's blanket waivers.

### **Emerging Authorities and Possible Additional Immunities**

It is certain that there will be additional authorities created to address the COVID-19 pandemic. For example, at the time of this writing, the United States Congress is working on a "Phase 4" bill to follow the CARES Act (which was "Phase 3" of the legislative response to COVID-19). As government bodies at the federal as well as state and local levels continue to address the pandemic, new laws may provide additional immunities and/or other protections for businesses.

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