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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2020-0016]

**Voluntary Agreement under Section 708 of the Defense Production Act;
Manufacture and Distribution of Critical Healthcare Resources Necessary to
Respond to a Pandemic**

AGENCY: Federal Emergency Management Agency, Homeland Security (DHS).

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) announces the formation of a voluntary agreement under Section 708 of the Defense Production Act for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic. This Notice contains the text of the Voluntary Agreement.

FOR FURTHER INFORMATION CONTACT: Harold Lucie, Joint DPA Office, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472-3184, telephone (202) 212-2900, and email FEMA-DPA@fema.dhs.gov.

SUPPLEMENTARY INFORMATION:

Authority

Section 708 of the Defense Production Act (DPA), 50 U.S.C. 4558, allows the President to provide for the formation of voluntary agreements by the private sector to help provide for the national defense. This authority was delegated to the Secretary of

Homeland Security generally in section 401 of Executive Order 13603,¹ “National Defense Resources Preparedness,” and specifically for response to COVID-19 in section 3 of Executive Order 13911,² “Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources To Respond to the Spread of COVID-19.” The Secretary of Homeland Security has delegated these authorities to the FEMA Administrator in Department of Homeland Security (DHS) Delegation 09052 Rev. 00, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency,” (Jan. 3, 2017), and DHS Delegation 09052 Rev. 00.1, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency” (Apr. 1, 2020), respectively.

Background

FEMA sought and received approval from the Attorney General, after consultation with the Federal Trade Commission (FTC), to begin consultation with the private sector, as required by Section 708(c)(2). Pursuant to that approval, on May 12, 2020, FEMA posted an announcement of a public meeting and request for comments to develop a Voluntary Agreement in the *Federal Register* (85 FR 28031). FEMA held a public meeting on May 21, 2020, and accepted public comments until June 5, 2020.³ FEMA received 34 public comments and considered these comments when preparing the Voluntary Agreement.⁴

¹ 77 FR 16651 (Mar. 22, 2012).

² 85 FR 18403 (Apr. 1, 2020).

³ The original comment period was extended to allow commentators additional time to respond. FEMA posted notices of extension to www.regulations.gov under the Docket ID for this notice, FEMA-2020-0016.

⁴ Available on www.regulations.gov under Docket ID for this notice.

The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the voluntary agreement may not reasonably be achieved through an agreement having less anticompetitive effect or without any voluntary agreement. Pursuant to Sec. 708(f)(1)(B) of the Defense Production Act, the Department of Justice is separately publishing this finding in this issue of the *Federal Register* as a notice. The FEMA Administrator, as the Sponsor of the agreement, has certified in writing that the agreement is necessary to help provide for the national defense.

**Text of the Voluntary Agreement, Manufacture and Distribution of Critical
Healthcare Resources Necessary to Respond to a Pandemic**

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Voluntary Agreement, MANUFACTURE AND DISTRIBUTION OF CRITICAL HEALTHCARE RESOURCES NECESSARY TO RESPOND TO A PANDEMIC

Preface

Pursuant to section 708 of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4558), the Federal Emergency Management Agency (FEMA) Administrator (Administrator), after consultation with the Secretary of the Department of Health and Human Services (HHS), the Attorney General of the United States (Attorney General), and the Chairman of the Federal Trade Commission (FTC), has developed this Voluntary Agreement (Agreement). This Agreement is intended to maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between the Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, and allocation and distribution of Critical Healthcare Resources. The activities contemplated by this Agreement are limited to those necessary to respond to a Pandemic, at the sole determination of FEMA. This Agreement affords Participants defenses to civil and criminal actions brought for violations of antitrust laws when carrying out this Agreement and an appropriate Plan of Action. This Agreement is intended to foster a close working relationship among FEMA, HHS, and the Participants to address national defense needs through cooperative action under the direction and supervision of FEMA. This Agreement, when implemented through a Plan of Action, affords Participants a safe harbor to exchange information, collaborate and adjust commercial operations as to particular products and services, when FEMA determines it

necessary for the national defense, and only to the extent necessary for the national defense.

I. Purpose

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs such that, pursuant to DPA section 708(c)(1), an agreement to collectively coordinate, plan and collaborate for the manufacture and distribution of personal protective equipment (PPE), Pharmaceuticals and other Critical Healthcare Resources is necessary for the national defense. This Agreement will maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between the Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, allocation and distribution of Critical Healthcare Resources. The activities included in this Agreement are limited to those necessary to respond to a Pandemic, at the sole determination, direction, and supervision of FEMA and implemented through Plans of Action.

II. Authorities

Section 708, Defense Production Act (50 U.S.C. 4558); sections 402(2) & 501(b), Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121-5207); sections 503(b)(2)(B) & 504(a)(10) & (16) of the Homeland Security Act of 2002 (6 U.S.C. 313(b)(2)(B), 314(a)(10) & (16)); sections 201, 301, National Emergencies Act (50 U.S.C. 1601 *et seq.*); section 319, Public Health Service Act (42 U.S.C. 247d); Executive Order (E.O.) 13911, 85 FR 18403 (Mar. 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic

Use, 85 FR 20195 (Apr. 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Agreement is necessary for the national defense.

III. General Provisions

A. Definitions

Administrator

The FEMA Administrator who, as a Presidentially appointed and Senate confirmed official, is the Sponsor of this Agreement. Pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, the Administrator proposes and provides for the development and carrying out of this Agreement. The Administrator is responsible for carrying out all duties and responsibilities required by 50 U.S.C. 4558 and 44 CFR part 332 and for appointing one or more Chairpersons to manage and administer the Committee and any Sub-Committee formed to carry out this Agreement.

Agreement

The Voluntary Agreement. Participants who have been invited to join and agreed to the terms of this Agreement as described in Section VII below may join the “Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic.”

Attendees

Subject matter experts, invited by the Chairperson to attend meetings authorized under this Agreement, to provide technical advice or to represent other Government agencies or interested parties. Attendees are not Members of the Committee.

Chairperson

FEMA senior executive, appointed by the Administrator, to chair the “Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic.” The Chairperson shall be responsible for the overall management and administration of the Committee, this Agreement, and Plans of Action developed under this Agreement while remaining under the supervision of the Administrator; may create one or more Sub-Committees, as approved by the Administrator; shall initiate, or approve in advance, each meeting held to discuss problems, determine policies, recommend actions, and make decisions necessary to carry out this Agreement; and otherwise shall carry out all duties and responsibilities assigned to him. The Administrator may appoint one or more co-Chairpersons to chair the Committee and Sub-Committees, as appropriate.

Committee

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under this Agreement. Provides Committee Members a forum to maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a Pandemic through integrated coordination, planning, and identification and development of Plans of Action needed to respond to a pandemic, including making recommendations on the creation of a Plan of Action.

Critical Healthcare Resources

All categories of health and medical resources for which production and distribution capacity is necessary to respond to a pandemic, including, but not limited

to, PPE, Pharmaceuticals, respiratory devices, vaccines, raw materials, supplies, and medical devices.

Documents

Any information, on paper or in electronic format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant.

Members

Collectively the Chairperson, Representatives, and Participants of the Committee. Jointly responsible for developing all decisions necessary to carry out this Agreement and to develop and execute Plans of Action under this Agreement.

Pandemic

A Pandemic is defined as an epidemic that has spread to human populations across a large geographic area that is subject to one or more declarations under the National Emergencies Act, the Public Health Service Act, or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or if the Administrator determines that one or more declarations is likely to occur and the epidemic poses a direct threat to the national defense or its preparedness programs. For example, Coronavirus Disease 2019 (COVID-19).

Participant

An individual, partnership, corporation, association, or private organization, other than a Federal agency, that has substantive capabilities, resources or expertise to carry out the purpose of this Agreement, that has been specifically invited to participate in this Agreement by the Chairperson, and that has applied and agreed to

the terms of this Agreement in Section VII below. “Participant” includes a corporate or non-corporate entity entering into this Agreement and all subsidiaries and affiliates of that entity in which that entity has 50 percent or more control either by stock ownership, board majority, or otherwise. The Administrator may invite Participants to join this Agreement at any time during its effective period.

Personal Protective Equipment

Objects that provide measures of safety protection for healthcare workers, first responders, critical infrastructure personnel and/or the general public for the response to the Pandemic. These PPE items may include, but are not limited to, face coverings, filtering facepiece respirators, face shields, isolation and surgical gowns, examination and surgical gloves, suits, and foot coverings.

Pharmaceuticals

All drugs defined under the Food, Drug, and Cosmetic Act, 21 U.S.C. 321(g), including biological products defined under the Public Health Service Act, 42 U.S.C. 262(i).

Plan of Action

A documented method, pursuant to 50 U.S.C. 4558(b)(2), proposed by FEMA and adopted by invited Participants, to implement this Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

Plan of Action Agreement

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action. Completing the Plan of Action Agreement confers

responsibilities on the Participant consistent with those articulated in the Plan of Action and affords Participants antitrust protections for actions taken consistent with that Plan of Action as described in Section IV below.

Point of Care

All categories of medical service providers necessary to respond to a pandemic, as determined by the Chairperson after consultation with the Members of the Committee. This may include, but is not limited to, Acute Care, First Responders, Nursing Homes, Private Hospitals, Public Hospitals, Veterans Administration Hospitals, Physician Offices, Dental Offices, Ambulatory Clinics, Pharmacies, Community Health Clinics, Laboratories, and other acute and non-acute care facilities responsible for healthcare.

Representatives

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other Federal agencies with equities in this Agreement, and empowered to speak on behalf of their agencies' interests. The Attorney General and the Chairman of the FTC, or their delegates, may also attend any meeting as a Representative.

Sub-Committee

A body formed by the Administrator from select Participants to implement a Plan of Action.

B. Committee Participation

The Committee established under this Agreement will consist of the (1) Chairperson, (2) Representatives from FEMA, HHS, DOJ, and other Federal agencies

with equities in this Agreement, and (3) Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Agreement. Other Attendees – invited by the Chairperson as subject matter experts to provide technical advice or to represent the interests of other Government agencies or interested parties – may also participate in Committee meetings. Collectively, the Chairperson, Representatives and Participants will serve as the Members of the Committee. Public notice will be provided as each Participant joins or withdraws from this Agreement. The list of Participants will be published annually in the *Federal Register*.

C. Effective Date and Duration of Participation

This Agreement is effective immediately upon the signature of the Participant or their authorized designees. This Agreement shall remain in effect until terminated in accordance with 44 CFR 332.4, or in any case, it shall be effective no more than five (5) years from the date the requirements of DPA section 708(f)(1) are satisfied as to the initial Voluntary Agreement regarding the manufacture and distribution of critical healthcare resources necessary to respond to a Pandemic, unless otherwise terminated pursuant to DPA section 708(h)(9) and 44 CFR 332.4 or extended as set forth in DPA section 708(f)(2). No action may take place under this Agreement until it is activated, as described in Section III(E.), below.

D. Withdrawal

Participants may withdraw from this Agreement at any point, subject to the fulfillment of obligations incurred under this Agreement prior to the date this agreement is terminated with regard to such Participant, by giving written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that

Participant's withdrawal. Following receipt of such notice, the Administrator will inform the other Participants of the date of the withdrawal.

Upon the effective date of the withdrawal, the Participant must cease all activities under this Agreement.

E. Plan of Action Activation and Deactivation

Upon occurrence of a Pandemic, the Administrator may authorize a Plan of Action and Sub-Committee for one or more specific Pandemic response workstreams, functional areas, or Critical Healthcare Resource national defense needs, e.g., a pharmaceuticals plan of action, or a PPE distribution plan of action, or a vaccine plan of action. The Administrator will invite a select group of Participants who are representative of the segment of the industry for which the Plan of Action is intended to participate on the Sub-Committee. The Plan of Action will be activated for each invited Participant when the Participant executes a Plan of Action Agreement. Actions taken by Participants to develop a Plan of Action and actions taken after executing a Plan of Action Agreement to collectively coordinate, plan and collaborate, pursuant to that Plan of Action and as directed and supervised by FEMA, will constitute action taken to develop and carry out this Agreement pursuant to 50 U.S.C. 4558(j).

Sub-Committees will meet only for the purposes specified in this Agreement and as provided for in writing by the Chairperson. They will report directly to the Committee regarding all actions taken by them, and any Plan of Action adopted by a Sub-Committee must be approved first by the Chairperson. A Plan of Action may not become effective unless and until the Attorney General (after consultation with the

Chairman of the Federal Trade Commission) finds, in writing, that such purpose(s) of the Plan of Action may not reasonably be achieved through a Plan of Action having less anticompetitive effects or without any Plan of Action and publishes such finding in the *Federal Register*. The Chairperson may appoint a Sub-Committee Chairperson to preside over each Sub-Committee as a delegate of the Chairperson; however, the Chairperson retains responsibility for all Sub-Committees and for administrative and record keeping requirements of any meetings held by such Sub-Committees, including providing public notice as required of any meetings.

When recommended by the Sub-Committee Chairperson, the Administrator will provide notice of a Plan of Action Deactivation. Any actions taken by Participants after the Deactivation date are outside the scope of Plan of Action Agreement and the Section IV antitrust defense is not available.

F. Rules and Regulations

Participants acknowledge and agree to comply with all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, the Department of Homeland Security, HHS, the Attorney General, and the FTC. FEMA has promulgated standards and procedures pertaining to voluntary agreements in 44 CFR part 332. The Administrator shall inform Participants of new rules and regulations as they are issued.

G. Modification and Amendment

The Administrator, after consultation with the Attorney General and the Chairman of the FTC, may terminate or modify, in writing, this Agreement or a Plan of Action at any time, and may remove Participants from this Agreement or a Plan of Action at any

time. Participants may propose modifications or amendments to this Agreement at any time. The Administrator shall inform Participants of modifications or amendments to this Agreement as they are issued. If a Participant indicates an intent to withdraw from the Agreement due to a modification or amendment of the Agreement, the Participant will not be required to perform actions directed by that modification or amendment.

The Attorney General, after consultation with the Chairman of the FTC and the Administrator, may terminate or modify, in writing, this Agreement or a Plan of Action at any time, and may remove Participants from this Agreement or a Plan of Action at any time. If the Attorney General decides to use this authority, the Attorney General will notify the Chairperson as soon as possible, who will in turn notify Participants.

H. Expenses

Participation in this Agreement does not confer funds to Participants, nor does it limit or prohibit any pre-existing source of funds. Unless otherwise specified, all expenses, administrative or otherwise, incurred by Participants associated with participation in this Agreement shall be borne exclusively by the Participants.

I. Record Keeping

The Chairperson shall have primary responsibility for maintaining records in accordance with 44 CFR part 332, and shall be the official custodian of records related to carrying out this Agreement. Each Participant shall maintain for 5 years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Participants or with any other member of the Committee, including drafts, related to the carrying out of this Agreement or any Plan of Action or incorporating data or information received in the course of carrying out this Agreement

or any Plan of Action. Each Participant agrees to produce to the Administrator, the Attorney General, and the Chairman of the FTC upon request any item that this section requires the Participant to maintain. Any record maintained in accordance with 44 CFR part 332 shall be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with DPA section 705(d), and 44 CFR 332.5.

IV. Antitrust Defense

Under the provisions of DPA subsection 708(j), each Participant in this Agreement shall have available as a defense to any civil or criminal action brought for violation of the antitrust laws (or any similar law of any State) with respect to any action to develop or carry out this Agreement or a Plan of Action, that such action was taken by the Participant in the course of developing or carrying out this Agreement or a Plan of Action, that the Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Participant acted in accordance with the terms of this Agreement and any relevant Plan of Action. Except in the case of actions taken to develop this Agreement or a Plan of Action, this defense shall be available only to the extent the Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Agreement or a Plan of Action.

This defense shall not apply to any action occurring after the termination of this Agreement or a Plan of Action. Immediately upon modification of this Agreement or a Plan of Action, no antitrust immunity shall apply to any subsequent action that is beyond the scope of the modified Agreement or Plan of Action. The Participant asserting the defense bears the burden of proof to establish the elements of the defense. The defense

shall not be available if the person against whom the defense is asserted shows that the action was taken for the purpose of violating the antitrust laws.

V. Terms and Conditions

Each Participant agrees to voluntarily collaborate with all Committee Members to recommend Plans of Action and Sub-Committees that will, at the direction of and under the supervision of FEMA, maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between the Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, and allocation and distribution of Critical Healthcare Resources. These efforts aim to promote efficiency and timeliness to mitigate shortages of Critical Healthcare Resources to respond to a Pandemic and to meet the overall demands of the healthcare and other selected critical infrastructure sectors, along with those demands necessary to continue all-level-of-government mission-essential functions.

As the sponsoring agency, FEMA will maintain oversight over Committee and Sub-Committee activities and direct and supervise actions taken to carry out this Agreement and subsequent Plans of Action, including by retaining decision-making authority over actions taken pursuant to this Agreement and subsequent Plans of Action to ensure such actions are necessary to address a direct threat to the national defense. The Department of Justice (DOJ) and the Chairman of the FTC will monitor activities of the Committee and Sub-Committees to ensure they execute their responsibilities in a manner consistent with this Agreement having the least anticompetitive effects possible.

A. Plan of Action Execution

Specific Member obligations and actions to be undertaken will only be provided for in individual Plans of Action, not in the Agreement. Activities taken to develop a Plan of Action or to implement a Plan of Action that has been activated pursuant to section III.E. above will provide Participants the antitrust defense described in section IV. Each Plan of Action will endeavor to clearly identify the conduct that Participants will undertake in carrying out the Plan of Action and that would be subject to the defense described in Section IV.

Each Plan of Action will describe what information Members will share, as directed by FEMA and under FEMA's supervision. Information will be used to create a common operating picture in furtherance of the Plan of Action's purpose and/or to promote overall situational awareness of Critical Healthcare Resource manufacturing and distribution activities.

Each Plan of Action, and information gathered pursuant to that plan, will be used to support one or more of the following objectives:

- (1) Facilitate maximum availability of Critical Healthcare Resources to end-users by deconflicting overlapping requirements for the collective Participant customer base;
- (2) Facilitate maximum availability of Critical Healthcare Resources to Members by deconflicting overlapping supply chain demands of Members;
- (3) Facilitate efficient distribution of Critical Healthcare Resources by deconflicting overlapping distribution chain activities of Members;
- (4) Inform where expansion of the manufacture of Critical Healthcare resources is necessary;
- (5) Identify and prioritize Critical Healthcare Resource requirements;

- (6) Validate Critical Healthcare Resource requirements;
- (7) Project future demand for Critical Healthcare Resource requirements.
- (8) Execute a collaborative manufacturing strategy to more efficiently make use of limited resources for key manufacturing lines of effort for Critical Healthcare Resources;
- (9) Collaborate in the voluntary Participant allocation of Critical Healthcare Resources nationwide;
- (10) Cooperate to the fullest extent possible to distribute Critical Healthcare Resources to locations most in need, as identified by FEMA;
- (11) Explore strategies for increased manufacturing of Critical Health Resources in or near the United States;
- (12) Carry out any other activities as determined and directed by FEMA necessary to address the Pandemic's direct threat to the national defense.

B. Information Management and Responsibilities

FEMA will request only that data and information from Participants that is necessary to meet the objectives of a Plan of Action. Upon signing a Plan of Action Agreement, participants should endeavor to cooperate to the greatest extent possible to share data and information necessary to meet the objectives of the Plan of Action.

The specific data requested, procedures for sharing that data, and data management and disposition will be tailored for each specific Plan of Action. Where feasible and to the greatest extent possible, FEMA will incorporate the following principles regarding data sharing into each Plan of Action:

- In general, Participants will not be asked to share competitively sensitive information directly with other Participants. Direct sharing of information among

Participants will be requested only when necessary and will be closely supervised by FEMA, including requiring appropriate safeguards regarding participant use and dissemination of other participants' data.

- If FEMA needs to share information with parties outside the Sub-Committee, FEMA will limit the amount and type of information shared to the greatest extent feasible and permitted by law, while still furthering the objectives of the Plan of Action.
- Prior to distribution within or outside the Sub-Committee, FEMA will aggregate and anonymize data in such a way that will maximize the effectiveness of the Plan of Action without compromising competitively sensitive information.
- Pursuant to 5 U.S.C. 552(b)(4) and 44 CFR 332.5, FEMA will withhold from disclosure under the Freedom of Information Act Participant trade secrets and commercial or financial information and will restrict Sub-Committee meeting attendance where necessary to protect trade secrets and commercial or financial information.
- Any party receiving competitively sensitive information through a Plan of Action shall use such information solely for the purposes outlined in the Plan of Action and take steps, such as imposing firewalls or tracking usage, to ensure such information is not used for any other purpose. Disclosure and use of competitively sensitive information will be limited to the greatest extent possible.
- At the conclusion of a Participant's involvement in a Plan of Action – due to the deactivation of the Plan of Action or due to the Participant's withdrawal or removal – each Participant will be requested to sequester any and all competitively sensitive information received through participation in the Plan of Action. This sequestration will include the deletion of all competitively sensitive information unless required to be kept

pursuant to the Record Keeping requirements as described *supra*, Section I, 44 CFR part 332, or any other provision of law.

C. Oversight

The Chairperson is responsible for ensuring the Attorney General, or suitable delegate(s) from DOJ, and the FTC Chairman, or suitable delegate(s) from the FTC, have awareness of activities under this Agreement, including Plan of Action activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chairman, or their delegates may attend Committee and Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Agreement or a Plan of Action. DOJ or FTC Representatives may request and review any proposed action by the Committee, Sub-Committee or Participants undertaken pursuant to this Agreement or Plan of Action, including the provision of data. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she shall provide warning and guidance to the Committee as soon as the potential issue is identified. If questions arise about the antitrust protections applicable to any particular action, FEMA may request DOJ, in consultation with the FTC, provide an opinion on the legality of the action under relevant DPA antitrust protections.

VI. Establishment of the Committee

There is established a Committee for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee) to provide the Federal Government and the Participants a forum to maximize the effectiveness of the manufacture and distribution of Critical Healthcare Resources nationwide to respond to a

Pandemic through integrated coordination, planning, and information sharing with FEMA. A Chairperson designated by the FEMA Administrator will convene and preside over the Committee. The Committee will not be used for widespread or collective exchange of information among members. These activities, if required, shall be done within individual Sub-Committees, and in accordance with an established Plan of Action. The Committee will not be used for contract negotiations or contract discussions between the Participants and the Federal Government; such negotiations or discussions will be in accordance with applicable Federal contracting policies and procedures. However, this shall not limit any discussion within a Sub-Committee about the operational utilization of existing and potential contracts between the Participants and Representatives when seeking to align their use with overall manufacturing and distribution efforts consistent with this Agreement and a Plan of Action.

The Committee will consist of designated Representatives from FEMA, HHS, other Federal agencies with equities in this Agreement, and each Participant. The Attorney General and Chairman of the FTC, or their delegates, may also join the Committee and attend meetings at their discretion. Attendees may also be invited at the discretion of the Chairperson as subject matter experts, to provide technical advice, or to represent other Government agencies, but will not be considered part of the Committee.

To the extent necessary to respond to the Pandemic and at the explicit direction of the Chairperson, the Committee Members will provide technical advice to each other as needed, share information collectively, identify and validate places and resources of the greatest need, project future manufacturing and distribution demands, collectively identify and resolve the allocation of scarce resources amongst all necessary public and

private sector domestic needs, and as necessary, share vendor, manufacturer and distribution information, and take any other necessary actions to maximize the timely manufacture and distribution of Critical Healthcare Resources as determined necessary by FEMA to respond to the Pandemic. The Chairperson or his or her designee, at the Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum coordination, efficiency, and effectiveness in the use of Member's resources and will create and execute Plans of Action as needed. All Participants will be invited to open Committee meetings. For selected Committee meetings, attendance may be limited to designated Participants to meet specific operational requirements.

The Committee Chairperson shall notify the Attorney General, the Chairman of the FTC, Representatives, and Participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be held to carry out this Agreement. Additionally, the Chairperson shall provide for publication in the *Federal Register* of a notice of the time, place, and nature of each meeting. If a meeting is open, a *Federal Register* notice will be published reasonably in advance of the meeting. The Chairman may restrict attendance at meetings only on the grounds outlined by 44 CFR 332.5(c)(1)-(3). If a meeting is closed, a *Federal Register* notice will be published within 10 days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Chairperson shall establish the agenda for each meeting, be responsible for adherence to the agenda, and provide for a written summary or other record of each meeting and provide copies of transcripts or other records to FEMA, the Attorney General, the Chairman of the FTC, and all Participants. The Chair shall take necessary

actions to protect from public disclosure any data discussed with or obtained from Participants which a Participant has identified as a trade secret or as privileged and confidential in accordance with DPA sections 708(h)(3) and 705(d), or which qualifies for withholding under 44 CFR 332.5.

The Administrator, in his or her sole discretion and after consultation with the Committee Members, will create Plans of Action and Sub-Committees for specific workstreams or functional areas requiring collective coordination, planning, and collaboration. These Sub-Committees shall be subject to the same rules, regulations and requirements of the Committee and any other rules or requirements deemed necessary by the Chairperson, the Administrator, or the Attorney General, after consultation with the Chairman of the FTC.

VII. Application and Agreement

The Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Voluntary Agreement entitled Committee for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Agreement) and to become a Participant in this Committee. This Agreement will be published in the *Federal Register*. This Agreement is authorized under section 708 of the Defense Production Act of 1950, as amended. Regulations governing this Agreement appear at 44 CFR part 332. The applicant, as Participant, agrees to comply with the provisions of section 708 of the Defense Production Act of 1950, as amended, the regulations at 44 CFR part 332, and the terms of this Agreement.

VIII. Assignment

No Participant may assign or transfer this Agreement, in whole or in part, or any protections, rights or obligations hereunder without the prior written consent of the Chairperson. When requested, the Chairperson will respond to written requests for consent within 10 business days of receipt.

(Company name)

(Name of authorized representative)

(Signature of authorized representative)

(Date)

Administrator (Sponsor)

(Date)

Pete Gaynor,

Administrator,

Federal Emergency Management Agency.