FEMA prepared this draft document, pursuant to 50 U.S.C. 4558 and 44 CFR 332.2, in furtherance of a proposal to sponsor and develop a voluntary agreement. It is a proposal and cannot be commenced until and if, pursuant to 50 U.S.C. 4558(f)(1)(B), it is approved by the Attorney General.

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 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 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. This Agreement is intended to foster a close working relationship among FEMA, HHS, and the Participants to address national defense needs through cooperative action. This Agreement 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. For the COVID-19 pandemic, this Agreement is active once the requirements of DPA section 708(f)(1) are satisfied and will remain active until the Administrator provides notice of a Pandemic Event Deactivation. For future pandemics, the Agreement will be activated and deactivated as described below.

I. Purpose

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs requiring, pursuant to DPA section 708(c)(1), that an agreement to collectively coordinate, plan and collaborate for the manufacture and distribution of 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 and direction of FEMA.

II. Authorities

Section 708, Defense Production Act (50 U.S.C. 4558); section 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.) 13909, 85 FR 16227 (March 18, 2020); Executive Order (E.O.) 13911, 85 FR 18403 (March 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 FR 20195 (April 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Agreement is necessary for the national defense. Pursuant to DPA section 708(f)(1)(B), the Attorney General, after consultation with the Chairman of the FTC, finds that the collective coordination, planning and collaboration for the manufacture and distribution of PPE,

Pharmaceuticals, and other Critical Healthcare Resources at the direction of FEMA to meet national defense requirements provided for in this Agreement cannot be provided through an agreement having fewer anticompetitive effects.

III. General Provisions

A. Definitions

Administrator

The Administrator of the Federal Emergency Management Agency and the Sponsor of this Agreement.

Attendees

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

Business Sensitive Needs

Proprietary or other similar business information, as identified by a Participant, that may fall under the exceptions found at 44 CFR 332.5(c)(1)-(3).

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 subcommittees, 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 carry out all duties and responsibilities provided to them. The Administrator may appoint one or more co-Chairpersons.

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, information sharing with FEMA, and allocation and distribution of these resources as determined necessary by and at the direction of FEMA. As approved by the Administrator, one or more subcommittees may be formed to carry out the work of the Committee, led by either the Chairperson or another federal government official fulfilling requirements provided for under 44 CFR 332.3.

Critical Healthcare Resources

Personal protective equipment (PPE), Pharmaceuticals, and other critical healthcare equipment, products, raw materials and supplies, including respiratory devices and vaccines, and

other medical devices that are not PPE, necessary to respond to a pandemic as designated by FEMA.

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. For example, Coronavirus Disease 2019 (COVID-19).

Participant

An individual, partnership, corporation, association, or private organization, other than a federal agency, which have substantive capabilities, resources or expertise to carry out the purpose of this Agreement, who have been specifically invited to participate in this Agreement by the Chairperson, and who have 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. To the extent necessary to respond to a Pandemic, the Chairperson shall endeavor to encourage participation by Participants that are reasonably representative of the appropriate industry or segment of that industry. The Administrator may invite Participants to join this Agreement at any time during its effective period.

Personal Protective Equipment

Objects that provide safety protection for healthcare workers, first responders, critical infrastructure personnel and 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

For the purposes of this Agreement, a pharmaceutical refers to a drug. A drug is defined as a substance recognized by certain official pharmacopoeias or formularies; a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; a substance (other than food) intended to affect the structure or any function of the body; or a substance intended for use as a component of a medicine, consistent with 21 U.S.C. 321(g). Biological products are included within this definition.

Plan of Action

Means any of one or more documented methods adopted by the Members of the Committee to implement this Agreement.

Point of Care

Categories of medical service providers, as determined at the sole discretion of the Chairperson after consultation with the Members of the Committee. They may include Acute Care, First Responders, Nursing Homes, Private Hospitals, Public Hospitals and Veterans Administration Hospitals.

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 agency's interests. The Attorney General and the Chairman of the FTC, or their delegates, may also attend any meeting as a Representative.

Sponsor

The FEMA Administrator who as a Presidentially appointed and Senate confirmed official, and pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, proposes and provides for the development and carrying out of this Agreement. The Sponsor 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 formed to carry out this Agreement.

B. 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, (3) Attendees invited by the Chairperson as subject matter experts to provide technical advice, or to represent the issues of other government agencies or interested parties, and (4) Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Agreement. 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 VI, 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, by giving written notice to the Administrator at least thirty (30) calendar days prior to the effective date of the 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. Withdrawal from this Agreement will not deprive a Participant of an antitrust defense otherwise available to it in accordance with DPA section 708 for the fulfillment of obligations incurred prior to withdrawal and otherwise eligible for such defense under the Agreement, pursuant to FEMA direction, and in accordance with the provisions of the DPA.

E. Pandemic Event Activation and Deactivation

This Agreement is active for the Covid-19 pandemic. The Agreement will remain active until the Administrator provides notice of a Pandemic Event Deactivation. For future pandemics, the Agreement will be activated and deactivated as described below.

Upon occurrence of a Pandemic, the Administrator may provide notice of a Pandemic Event Activation activating this Agreement for the Pandemic, which shall include an activation date. Such activation is required to afford Participants the antitrust defense protections under Section IV of this Agreement. Participants may take action under this Agreement only when the Administrator has provided notice of a Pandemic Event Activation for a specific event. When recommended by the Chairperson, the Administrator will provide notice of a Pandemic Event Deactivation, which shall include an activation date. Any actions taken by Participants before the activation date included in the notice of a Pandemic Event Activation, or after the deactivation date included in the notice of a Pandemic Event Deactivation, are outside the scope of this Agreement and the Section IV antitrust defense is not available.

F. Rules and Regulations

Participants acknowledge and agree to abide by all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, 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 Plan of Action at any time, and

may remove Participants from the agreement 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.

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

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 five years from the deactivation date included in the notice of a Pandemic Event Deactivation or the Participant's Withdrawal all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Participants or with any other member of the industry, including drafts, related to the carrying out of this Agreement or incorporating data or information received in the course of carrying out this Agreement. 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(e), 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 act or omission to act necessary to develop or carry out this Agreement while there is a Pandemic Event Activation, that such act or omission to act was taken by the Participant in the course of developing or carrying out this Agreement, with the oversight and approval by the Chairperson or other designated FEMA official, that the Participant fully complied with the provisions of the DPA and the rules promulgated thereunder, and that the Participant acted in accordance with the terms of this Agreement.

Except for actions taken to develop this Agreement, this antitrust defense shall not be available to a Participant for any act or omission occurring before the latter of the date the

Participant entered into this Agreement and the activation date included in the notice of a Pandemic Event Activation, after the deactivation date included in the notice of Pandemic Event Deactivation, or without the oversight and approval by and not at the direction of the Chairperson or other designated FEMA official. For actions taken to develop this Agreement, this defense shall be available in accordance with DPA subsection (j). If the Participant has withdrawn from this Agreement, this defense shall not be available for any action occurring after the effective date of withdrawal. This defense shall not be available, upon the modification of this Agreement, with respect to any subsequent act or omission that is beyond the scope of the modified Agreement, except that no such termination or modification shall be accomplished in a way that will deprive Participants of this antitrust defense for the fulfillment of obligations incurred. This defense shall be available only if, and only to the extent that the Participants asserting it demonstrate that, the action, which includes a discussion or agreement, was within the scope of this Agreement and taken at the direction of FEMA and with appropriate FEMA oversight and approval. The person asserting the defense bears the burden of proof. The defense shall not be available if the person against whom the defense is asserted shows that the action was taken for a purpose other than to carry out the purposes of this Agreement. Notwithstanding the foregoing, Participants may not assert this defense in response to any investigation by the DOJ or FTC pending at the time of the activation date, unless granted a specific waiver by the Attorney General or Chairman of the FTC; any request for such a waiver shall be submitted as soon as practicable under the circumstances.

V. Terms and Conditions

Each Participant agrees to voluntarily collaborate with all Committee Members, at the direction of and under the supervision of FEMA, 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, 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, as determined by the Committee, along with those demands necessary to continue all-level-of-government mission essential functions. The Committee will attempt to fulfill this direction through engaging in the activities listed in this section, and as necessary, creating and executing one or more Plans of Action to carry out this Agreement.

As the sponsoring agency, FEMA will maintain oversight over Committee activities and retain decision-making authority over actions taken pursuant to this Agreement or 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 to ensure the Committee executes its responsibilities in a manner consistent with this Agreement having the least anticompetitive effects possible.

A. Share Information Related to the Following Joint Enterprises

When directed by FEMA and under FEMA's supervision, members will share relevant information to the extent necessary to create a common operating picture for overall situational awareness of Critical Healthcare Resource manufacturing and distribution activities including to 1) deconflict overlapping requirements for the collective Participant customer base, 2) deconflict overlapping supply chain demands of Members, 3) deconflict overlapping distribution chain activities of Members, and 4) to inform where expansion of the manufacture of Critical Healthcare Resources is necessary to mitigate the effects of shortages on the mission essential functions of all levels of government, as determined by FEMA in consultation with HHS.

Participants will not share competitively sensitive information directly with one another absent specific direction from FEMA.

B. Identify and Prioritize Critical Healthcare Resource Requirements

When directed by FEMA and under FEMA's supervision, members will share relevant information to the extent necessary to create a common operating picture to identify and prioritize for FEMA the resource requirements for 1) Point of Care categories, 2) geographic locations or areas, 3) any Critical Healthcare Resources subject to oversight by the Committee, and 4) non-healthcare critical sectors and non-traditional PPE and Pharmaceutical consumers. In addition, the Members will commit to sharing information to identify, resource and advance manufacturing lines of effort for Critical Healthcare Resources.

C. Validate Critical Healthcare Resource Requirements

When directed by FEMA and under FEMA's supervision, members will share information to the extent necessary to validate the demand requirements from all economic sectors identified and selected by the Committee for the distribution of Critical Healthcare Resources in response to the Pandemic.

D. Project Future Demand for Critical Healthcare Resource Requirements

When directed by FEMA and under FEMA's supervision, members will share information with FEMA to the extent necessary to project the future demand for Critical Healthcare Resources for the lifecycle of the Pandemic.

E. Manufacture of Critical Healthcare Resources

When directed by FEMA and under FEMA's supervision, members will cooperate to the fullest extent possible in executing a collaborative manufacturing strategy to more efficiently make use of limited resources for key manufacturing lines of effort for Critical Healthcare Resources. This includes sharing and potentially pooling common storage, logistics, transportation and other operational capabilities necessary to reduce redundant operations and to maximize the timely manufacture of Critical Healthcare Resources.

F. Joint Allocation of Critical Healthcare Resources

When directed by FEMA and under FEMA's supervision, members will collaborate in the voluntary Participant allocation of Critical Healthcare Resources nationwide.

G. Distribution of Critical Healthcare Resources

When directed by FEMA and under FEMA's supervision, members will cooperate to the fullest extent possible to distribute Critical Healthcare Resources to locations most in need, as identified by FEMA. This includes sharing and potentially pooling common storage, logistics, transportation and other operational capabilities necessary to reduce redundant operations and to maximize timely distribution nationwide.

H. Create One or More Plans of Action

Members will issue one or more Plans of Action, as determined necessary by the Chairperson, to carry out this Agreement in accordance with 50 U.S.C. 4558. The Chairperson may determine, for example, that the Committee's methods for addressing PPE manufacturing and distribution require documentation in a Plan of Action different from a Plan of Action to document the Committee's methods for addressing Pharmaceuticals.

I. Other Activities Necessary to Address the Pandemic's Direct Threat to the National Defense, as Determined and Directed by FEMA.

Members will cooperate to the fullest extent possible in carrying out any other activities identified by the Committee that, as determined and directed by FEMA, are necessary to address the Pandemic's direct threat to the national defense.

J. Information Management and Responsibilities

FEMA will request only that data and information from Participants which is necessary to meet the objectives outlined above, or other objectives not specifically listed that are consistent with the objectives of this Agreement or subsequent plans of action. Participants should endeavor to cooperate and share such data and information with FEMA to the greatest extent possible.

Participants shall not share competitively sensitive information directly with other Participants unless specifically directed by FEMA. Otherwise, all information requested by FEMA, including that covered by Business Sensitive Needs, shall be shared with the Chairperson or other designated FEMA official. This information shall be aggregated in such a way as to maximize the awareness and effectiveness of the distribution of healthcare resources nationwide without compromising sensitive business information.

Where FEMA needs to share information with parties outside the Committee, FEMA will limit the amount of information shared and the recipients of the information to the greatest extent feasible and permitted by law, while still consistent with carrying out relevant activities under this Agreement. Pursuant to 50 U.S.C. 4558(e)(3)(D) and (G), 5 U.S.C. 552(b)(4), 5 U.S.C.

552b(c)(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 Committee and any sub-committee meeting attendance where necessary to protect trade secrets and commercial or financial information. FEMA will endeavor to use data-protection practices to limit the spread of any sensitive information shared under this Agreement.

Participants shall not solicit nor accept competitively sensitive information from FEMA or any parties unless necessary to achieve a FEMA mandated objective under this Agreement and at the direction and under the supervision of FEMA. Participants receiving competitively sensitive information from other Participants or from FEMA shall track the use of such information and the individuals who receive such information and limit the disclosure of such information to parties approved by FEMA. Participants may not use or disclose the competitively sensitive information for any purpose other than as expressly permitted by FEMA. Participants shall firewall competitively sensitive information to prevent any other use, and such firewall must have proper technological safeguards in place to ensure that no other person may accidentally or intentionally access it. Any Participant who receives competitively sensitive information in the course of activities under this Agreement from other Participants shall store the information behind a firewall or use other appropriate data-protection mechanisms and will not share this information without express consent of the party providing the data. Upon request, participants agree to produce in a timely manner to the Administrator, the Attorney General, and the Chairman of the FTC details regarding the Participant's firewall and data-protection mechanisms, and implement changes as the Administrator, the Attorney General or the Chairman of the FTC find necessary. Such details and changes may be requested and implemented prior to or after the receipt of competitively sensitive information at the discretion of the Administrator, the Attorney General or the Chairman of the FTC as the particular circumstances allow.

No later than 30 days after the deactivation date included in the notice of Pandemic Event Deactivation or effective date of a withdrawal, all Participants or, in the case of a withdrawal, the withdrawing Participant shall sequester any and all competitively sensitive information shared with them during the Activation, regardless of source and without any explicit request by FEMA or any other Participant, to ensure such information is not used in ongoing or future Participant activities. Such sequestration shall include the deletion of all competitively sensitive information received that is not required to be kept pursuant to the Record Keeping requirements as described *supra*, Section I, or 44 CFR part 332. Upon sequestration, the Participant shall submit to the Chairperson a written statement certifying the sequestration of competitively sensitive information. FEMA will retain copies of all information provided pursuant to this Agreement, in accordance with relevant recordkeeping statutes and regulations.

K. Oversight

The Chairperson is responsible for ensuring the Attorney General, or suitable delegate(s) from the DOJ, and the FTC Chairman, or suitable delegate(s) from the FTC, have awareness of activities under this Agreement, including activation, de-activation, and scheduling of meetings. The Attorney General, the FTC Chairman, or their delegates may attend Committee meetings

and request to be apprised on any activities taken in accordance with activities under this Agreement. DOJ Representatives may request and review any proposed action undertaken pursuant to this Agreement or subsequent plans 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 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 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.

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 the issues of 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 ten 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 privileged and confidential in accordance with DPA sections 708(h)(3) and 705(e), or which qualifies for withholding under 44 CFR 332.5.

The Chairperson, in his or her sole discretion and after consultation with the Committee Members, may also create one or more subcommittees 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. For instance, a subcommittee may be created specifically for the vertically integrated manufacture and distribution needs of a specific type of PPE. The subcommittees 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 subcommittee must be approved first by the Chairperson. The Chairperson may appoint a Subcommittee Chairperson for each subcommittee to preside over the subcommittee as a delegate of the Chairperson; however, the Chairperson retains ultimate responsibility for all subcommittees and for administerial and record keeping requirements of any meetings held by such subcommittees, including providing public notice as required of any meetings.

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. The text of said 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; Notice of Change of Control

No Participant may assign or transfer this Agreement, in whole or in part, or any protections, rights or obligations hereunder, whether by merger, operation of law or otherwise without the prior written consent of the Chairperson. Any changes of ownership or control of a Participant or a business entity within a Participant shall be deemed an assignment for purposes of this section. If a Participant becomes aware that an assignment has or will occur, the Participant shall notify the Chairperson within 30 days.

_____

(Company name)

_____

(Name of authorized representative)

_____

(Signature of authorized representative)

_____

(Date)

_____

(Sponsor)

_____

(Date)