Defense Production Act Voluntary Agreement Report to Congress

Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic

Calendar Year 2020 Report to Congress
August 10, 2021

FEMA

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Message from the FEMA Administrator

I am pleased to present the following report, The Defense Production Act Voluntary Agreement Report to Congress, for Calendar Year (CY) 2020. The Report was prepared by the Federal Emergency Management Agency (FEMA) and is being submitted to the President and the Congress, in accordance with subsection 708(l) of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. § 4558(l)).

Pursuant to statutory requirements, this report is being provided to the following Members of Congress:

The Honorable Sherrod Brown
Chairman, Senate Committee on Banking, Housing, and Urban Affairs

The Honorable Patrick J. Toomey
Ranking Member, Senate Committee on Banking, Housing, and Urban Affairs

The Honorable Maxine Waters
Chairwoman, House Committee on Financial Services

The Honorable Patrick T. McHenry
Ranking Member, House Committee on Financial Services

Inquiries regarding this report may be directed to FEMA's Congressional and Intergovernmental Affairs Division by telephone at (202) 646-4500.

Sincerely,

Deanne Criswell
FEMA Administrator

Executive Summary

FEMA's implementation of a voluntary agreement under the Defense Production Act (DPA) sets a historic precedent as the first time a civilian federal agency has carried out this authority. This agreement is a major step towards providing unity of effort between the private sector and the Federal Government to ensure that critical health and medical supplies and resources reach the American public during a pandemic.

Our country has not faced a shortage of resources like this in many decades, going back before the creation of FEMA in 1979. The DPA has its roots in the War Powers Acts of World War II. The Defense Production Act was signed at the start of the Korean War in 1950. Since then, the law has evolved and been reauthorized over the years to its current incarnation. The definition of national defense now includes emergency preparedness activities conducted under title VI of The Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. §§ 5195 et seq.).

The three main authorities of the DPA used to promote the national defense include: the ability of the federal government to prioritize contracts for critical supplies and allocate materials, services, and facilities; the authority to expand and incentivize manufacturing; and the one this report is focused on: establishing a Voluntary Agreement with the private sector to provide needed supplies and resources while offering antitrust protection.

In the broadest sense, this agreement, called "the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic," brings the government and the private sector together to voluntarily focus on solving specific problems. This agreement allows communication within and across industries and federal government agencies, and throughout all phases of supply chains, to benefit the Nation's response to COVID-19 or any future pandemic.

Since the Department of Justice (DOJ), in consultation with the Federal Trade Commission (FTC), authorized this Voluntary Agreement in August 2020, FEMA and the agreement participants have developed Sub-Committees to address several resource gaps for COVID-19. We developed a Plan of Action for Personal Protective Equipment, called the National Strategy for the Manufacture, Allocation and Distribution of Personal Protective Equipment (PPE) and other Critical Healthcare Resources to Respond to COVID-19. We anticipate the creation of other Plans of Action for the ongoing response to the pandemic, which will include support for the national vaccination campaign.

FEMA thanks all the manufacturers, distributors, and industry partners who have contributed to the nation's response to COVID-19, including those outside this agreement. We are fortunate to have this authority and structure to protect and provide for our country.

1. Introduction

This report describes the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement) and the Plan of Action to Establish a National Strategy for the Manufacture, Allocation and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 (henceforth "PPE Plan of Action"), both established in 2020. The Voluntary Agreement aims to maximize the effectiveness of the manufacture and distribution of critical healthcare resources throughout the United States to respond to a pandemic by establishing unity of effort between the participants in the Agreement ("Participants") and the Federal Government for integrated coordination, planning, and information sharing.

Subsection 708(l) provides that the individual or individuals designated by the President in subsection 708(c)(2) shall submit to the President and the Congress at least once every year a report describing each Voluntary Agreement or Plan of Action in effect and its contribution to provide for the national defense. The President has delegated the President's authority under section 708(c)(1) to provide for the making of voluntary agreements to the Secretary of Homeland Security (Executive Order 13603), who, in turn, has re-delegated this authority and the associated responsibilities to the FEMA Administrator.

The Voluntary Agreement described in this report is intended to foster a close working relationship among FEMA, the Department of Health and Human Services (HHS), other federal agencies and the private sector. The participants in this agreement address national defense[1] needs through cooperative action under the direction and supervision of FEMA. The purpose of this agreement is to help optimize the manufacture and distribution of critical healthcare resources nationwide to respond to pandemics, in general, and the COVID-19 pandemic, specifically. The participants in the agreement may exchange information, collaborate, or adjust commercial operations in the interest of the national defense and will be afforded antitrust protections for certain actions taken under the agreement.

2. Developing the Voluntary Agreement

The idea for a Voluntary Agreement to maximize production and distribution of healthcare resources to address the Coronavirus Disease 2019 (COVID-19) pandemic grew from the work of the Joint Defense Production Act Office and the FEMA COVID-19 Supply Chain Task Force. The Joint DPA Office, composed of staff from the Department of Homeland Security (DHS) and FEMA, HHS and the Department of Defense (DOD), including the Defense Logistics Agency, was established in March 2020 to support use of DPA authorities in response to the pandemic. The Supply Chain Task Force was created at the same time to help maximize the availability of critical protective and lifesaving resources to respond to the pandemic.

[1] As defined in DPA section 702: "The term 'national defense' means programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. Such term includes emergency preparedness activities conducted pursuant to title VI of The Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. 5195 et seq.] and critical infrastructure protection and restoration."

With FEMA's Supply Chain Task Force slated to transition to HHS as an advisory group in June 2020, FEMA proposed developing a Voluntary Agreement under the DPA as an additional tool to maximize coordination with the private sector for critical resources during a pandemic. The proposal for a Voluntary Agreement was submitted for review and approval by the Attorney General on April 13, 2020. DPA subsection 708(c)(2) requires the sponsor of a proposed Voluntary Agreement to consult with the DOJ Attorney General and with the FTC about the agreement not less than ten days before consulting with any potential participants in the agreement.

On May 4, 2020, the Attorney General provided written approval for the FEMA Administrator to begin consultations with potential participants in the proposed Voluntary Agreement. On May 12, 2020, FEMA provided notice of a public meeting to "Develop Pandemic Response; Voluntary Agreement" remotely via tele/web conference. On May 19, 2020, FEMA posted a draft agreement for comment in the Federal Register. On May 21, 2020, the virtual public meeting was held."[2] During that meeting, public commentary was permitted by pre-registered participants and the comment submission period was extended until June 5, 2020.

FEMA adjudicated the public comments, made appropriate revisions to the draft agreement, and sent the updated draft agreement to the DOJ for review. DOJ concurred with the updated draft on June 25, 2020. On June 26, 2020, the FEMA Administrator submitted a request to the Attorney General for the written finding required by law that the purpose of the proposed agreement may not reasonably be achieved with less anticompetitive effect or without a Voluntary Agreement in place. On June 30, 2020, DOJ began consultations with the Federal Trade Commission regarding the proposed agreement, as required by DPA subsection 708(f)(1)(B).

In July 2020, DOJ informed FEMA that the Attorney General was ready to approve the agreement with several edits; FEMA promptly revised the agreement and resubmitted it for the required finding.

On August 5, the Attorney General provided the finding required by DPA subsection 708(f)(1)(B). After receipt of the finding, the FEMA Administrator, as Sponsor of the Agreement, appointed the FEMA Associate Administrator for the Office of Policy and Program Analysis and the FEMA Associate Administrator for the Office of Response and Recovery to co-chair the Committee established by the agreement and directed them to take immediate steps to invite interested entities to participate.

On August 17, 2020, FEMA publicly announced the formation of the 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 in the Federal Register. The Voluntary Agreement is effective until August 17, 2025, unless terminated prior to that date, and may be extended subject to additional approval by the Attorney General after consultation with the Chairman of the Federal Trade Commission. The Agreement may be used to prepare for or respond to any pandemic, including COVID-19, during that time.

[2] DPA subsection 708(e)(3)(B) requires that notice of any meeting to establish a Voluntary Agreement shall be published in the Federal Register "at least seven days prior to any such meeting."

FEMA's Office of Policy and Program Analysis and Office of Response and Recovery worked together to execute a strategy on how to engage with the Voluntary Agreement stakeholders. This included devising an appropriate organizational structure representing federal and non-federal representatives, drafting a standard operating procedure for execution of the agreement and creation of any relevant plans of action needed to respond to COVID-19. FEMA also drafted the PPE Plan of Action, the first Plan of Action under the voluntary agreement.

On October 13, 2020, FEMA held the second public meeting to "Implement Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act." The first part of the meeting was open to the public. To facilitate public participation, members of the public were invited to provide written comments on the issues to be considered at the meeting. FEMA received 34 public comments: 6 individuals and 23 companies. Most of the comments supported the agreement. No public comment advocated against the creation of the agreement.

On November 25, 2020, FEMA submitted a request to DOJ asking that they issue a determination on the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to satisfy the standards set forth in section 708(f)(1)(B) of the Defense Production Act, 50 U.S.C. § 4558(f)(1)(B).

On December 7, 2020, and in accordance with subsection 708(f)(1)(A), the Plan of Action was transmitted to Congress.

In addition, FEMA coordinated the following meetings and actions:

- December 3, 2020: Notification of FEMA Voluntary Agreement Coordinating Group
- December 4, 2020: Notification of Federal Voluntary Agreement Representative Group
- December 8, 2020: Filed Public Notification in the Federal Register and invitations distributed for the PPE Plan of Action
- December 9, 2020: PPE Plan of Action Signatory Deadline for Industry
- December 14, 2020: First Meeting of the Requirements Sub-Committee under the PPE Plan of Action
- December 16, 2020: Second Meeting of the Requirements Sub-Committee
- December 17, 2020: Federal Voluntary Agreement Representative Group Meeting
- December 18, 2020: Third Meeting of the Requirements Sub-Committee
- December 21, 2020: Fourth Meeting of the Requirements Sub-Committee
- December 22, 2020: Federal Voluntary Agreement Representative Group Meeting

During January 2021, FEMA coordinated the following meetings and actions:

- January 6, 2021: First Meeting of the N95/Other Medical Respirators Sub-Committee
- January 7, 2021: First Meeting of the Gloves Sub-Committee
- January 8, 2021: Fifth Meeting of the Requirements Sub-Committee
- January 13, 2021: Federal Voluntary Agreement Representative Group Meeting
- January 15, 2021: Meeting to Implement Pandemic Response Voluntary Agreement Under the Section 708 of the Defense Production Act

3. Implementing the Voluntary Agreement

3.1 Participants in the Voluntary Agreement

The Voluntary Agreement is facilitated by FEMA in consultation with HHS and supported with the appropriate Federal departments and agencies that can work with industry to ensure optimal flow of goods, services, and healthcare supplies for COVID-19 and any pandemic over the next five years.

Effective coordination and interagency support are essential for the Voluntary Agreement to be effective in partnership with industry. FEMA's role is dependent upon industry, interagency coordination, and requirements of states' supply and demand of medical resources necessary to respond to COVID-19 or another pandemic under exigent circumstances.[3]
Implementing this authority enables operational resilience for public health, economic and national security and is based on addressing specific challenges of deeper information sharing. The only previous usage of this authority was undertaken by the Maritime Administration and took seven years to implement.

The Voluntary Agreement Representative Group (VARG) is made up of three main categories of the Federal Government: Statutory Representatives, Permanent Federal Representatives, and Advisory Representatives. Statutory Representatives' attendance is required by the statute and their participation is limited to advisory roles related to anti-trust advice. Statutory Representatives come from two agencies: DOJ and FTC. Permanent Federal Representatives include officials from FEMA, HHS, the Department of Defense (DOD), and Veteran's Affairs (VA). Advisory Representatives include employees from the DHS, Cybersecurity Infrastructure Security Agency (CISA), and the Department of Commerce (DOC) as well as other Permanent Federal Member Subcomponents.

The VARG works with Industry Participants and Advisory Attendees to implement the Voluntary Agreement. Industry Participants are identified as companies with significant scope and capability to carry out objectives. Advisory Attendees are subject matter experts, trade associations, and other advocacy groups invited to observe or to provide information to carry out Committee or Sub-Committee objectives. Participants in the Voluntary Agreement are listed in Appendix B.

3.2 Plan of Action

The Voluntary Agreement will be implemented through a series of Plans of Actions, each of which focuses on a single aspect of COVID-19 response. These Plans of Action may target sector-specific industries, such as medical supplies and resources, and keep actions narrowly tailored to respond quickly during an emergency. In addition, sector-specific plans allow

[3] Exigent Circumstances: As determined by the Chairperson, the actual or forecasted shortage of a particular type or types of PPE which likely cannot be fulfilled via usual market mechanisms for an acute, critical time period, and where immediate and substantial harm is projected to occur from lack of intervention.

participants to review all relevant information, including the scope of the requested work and information, prior to commitment.

The first Plan of Action under the Voluntary Agreement is designed to *"Establish a National Strategy for the Manufacture, Allocation and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19*." The text of the Plan of Action is included in Appendix C and was transmitted to Congress on December 7, 2020, in accordance with DPA subsection 708(f)(1)(A). Participants of this Plan of Action are listed in Appendix D.

The primary goal of the plan is to create a mechanism to meet immediately exigent PPE requests anywhere in the Nation and to ensure that actions to support PPE stockpiling and reserves do not interfere with immediate needs of healthcare providers or other potential PPE recipients. To this end, the plan calls for creation of the following five Sub-Committees, each focused on maximizing the manufacture and efficient distribution of critical PPE:

(1) Sub-Committee to Define COVID-19 PPE Requirements,
(2) Sub-Committee for N-95 and other Medical Respirators,
(3) Sub-Committee for Gloves,
(4) Sub-Committee for Gowns, and
(5) Sub-Committee for Eye and Facial Coverings.

The Plan of Action is designed to foster a close working relationship amongst FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active leadership and coordination of FEMA.

3.2.1 Objectives

Each Sub-Committee has the following objectives for the PPE item(s) within its scope:

A. Optimize the timely production of sufficient quantities of PPE to reduce loss of life and transmission of the COVID-19 virus.
B. Ensure PPE is distributed effectively across the whole community nationally based on risk.
C. Balance restoration and maintenance of the Nation's stockpile of PPE with near-term requirements.
D. Establish a process for FEMA adjudication and allocation of PPE nationwide.
E. Ensure ongoing competition in the manufacture and distribution of PPE to the greatest extent possible under the DPA.

3.2.2 Actions

Sub-Committee Participants may be asked to support these objectives by taking the following actions:

A. Assist in identifying types of PPE to be included within the Sub-Committee's jurisdiction.

B. Assist in creating a prioritized list of PPE End-Users by categories for each type of critical PPE identified by the Sub-Committee.
C. Evaluate the domestic supply of PPE and identify when the expansion of the domestic manufacture of PPE may be necessary.
D. Provide information and validate demand projections for PPE.
E. Create a process for and collaborate in the adjudication of competing claims for PPE from end-users.
F. Prepare a general strategy to accomplish the activities in exigent circumstances.
G. In exigent circumstances, with review and concurrence of DOJ in consultation with FTC as practical:

    - Facilitate maximum availability of PPE to the Nation or particular geographies by deconflicting overlapping demands from the collective Participants' customer base.
    - Facilitate maximum availability of PPE to the Nation or particular geographies by deconflicting overlapping supply chain demands placed on Sub-Committee Members.
    - Facilitate the efficient distribution of PPE by deconflicting overlapping distribution chain activities of Sub-Committee Members.
    - Create a process for and collaborate in the allocation and adjudication of PPE nationwide or in particular geographies.
    - Create a process for and collaborate in meeting any other exigent requirements throughout the Nation or particular geographies consistent with the overall strategy prepared by the Sub-Committee.

H. Provide data and information necessary to validate the efforts of the Sub-Committee, including the actual and planned amounts of PPE to be distributed throughout the Nation.
I. Provide feedback to the Sub-Committee on the outcomes of the collective efforts of the Sub-Committee Members and any impediments or bottlenecks.
J. Provide advice regarding possible additional Participants to join the Plan of Action and the Sub-Committee.
K. Carry out other activities regarding critical PPE as identified by the Sub-Committees under the Plan.

3.2.3 Achievements in Support of the National Defense

This Voluntary Agreement has created a partnership between federal agencies and 61 private sector signatories as of the third public meeting in January 2021. The Plan of Action for PPE has 28 signatories and is broken down into five (5) subcommittees (as noted in Section 2 above). In addition, for this Plan of Action, the Participants were asked to provide their top recommendations for implementation, which resulted in 74 responses.

The recommendations were divided into the following major categories:

- **Prioritization**: Sub-Committees for N95s/other Medical Respirators and Gloves to move forward.
- **Investment**: Significant investment in domestic capacity is requested across industry.
- **Supply Chain**: Develop a better understanding of the PPE supply chain (raw materials, manufacturers, distribution, end-user, black market) to optimize timely production and distribution.
- **Stockpile**: Stockpiling needs to be tailored for the end-user and informed by data.
- **Demand**: Forecast demand needs to be understood by all involved in the supply chain and demand-targets need to be developed.
- **Innovation**: In addition to reinforcing standards already available for existing PPE, the appropriate governmental entity needs to provide guidance for effective availability of PPE; including new categories or new technologies for extension of use.

FEMA continues to work with private sector participants to refine this list of priority topics and is in the process of developing additional Plans of Action to implement the Voluntary Agreement.

Currently, the Requirements, Gloves, and Respirator Sub-Committees are actively working to identify near term actions for supporting needs for these PPE items.

As we move forward, FEMA's Office of Business, Industry, and Infrastructure Integration (OB3I) will be the daily touchpoint on the Voluntary Agreement and associated Plans of Action as they are developed in consultation with industry participants and the Federal departments and agencies.

As the Voluntary Agreement and supporting implementation of Plans of Action was not a foreseeable requirement at the beginning of 2020, FEMA is adjusting resourcing to meet the challenges for COVID-19 and the five-year duration of the Agreement.

Appendix A. Voluntary Agreement

Text of the 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.

A. 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.

B. 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.

C. General Provisions

1) Definitions

a. 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.

b. 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."

c. 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.

d. 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.

e. 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.

f. 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.

g. 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.

h. 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.

i. 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).

j. 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.

k. 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.

l. 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).

m. 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.

n. 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.

o. 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.

p. 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.

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

2) 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**.

3) 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.

4) 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.

5) 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 administerial 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.

6) 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.

7) 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.

8) 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.

9) 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.

D. 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.

E. 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.

1) 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:

a. Facilitate maximum availability of Critical Healthcare Resources to end-users by deconflicting overlapping requirements for the collective Participant customer base;
b. Facilitate maximum availability of Critical Healthcare Resources to Members by deconflicting overlapping supply chain demands of Members;
c. Facilitate efficient distribution of Critical Healthcare Resources by deconflicting overlapping distribution chain activities of Members;
d. Inform where expansion of the manufacture of Critical Healthcare resources is necessary;
e. Identify and prioritize Critical Healthcare Resource requirements;
f. Validate Critical Healthcare Resource requirements;
g. Project future demand for Critical Healthcare Resource requirements.

h. Execute a collaborative manufacturing strategy to make use of limited resources more efficiently for key manufacturing lines of effort for Critical Healthcare Resources;
i. Collaborate in the voluntary Participant allocation of Critical Healthcare Resources nationwide;
j. Cooperate to the fullest extent possible to distribute Critical Healthcare Resources to locations most in need, as identified by FEMA;
k. Explore strategies for increased manufacturing of Critical Health Resources in or near the United States;
l. Carry out any other activities as determined and directed by FEMA necessary to address the Pandemic's direct threat to the national defense.

2) 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.

3) 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.

F. 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.

G. 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.

H. 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.

This document was published to the Federal Register in this location:

- ***Voluntary Agreement:*** *https://www.federalregister.gov/documents/2020/08/17/2020-18005/voluntary-agreement-under-section-708-of-the-defense-production-act-manufacture-and-distribution-of*
- ***Supporting Documentation:*** *https://www.regulations.gov/docket/FEMA-2020-0016/document*

Appendix B. Participants in the Voluntary Agreement

As of <u>October 13, 2020</u>, the "Meeting to Implement the Voluntary Agreement Participants" list was as follows (50 companies total; 39 Participants and 11 Attendees):

Participant:	**Attendee:**
3M	Advanced Medical Technology Association
Amerisource Bergen	American Hospital Association (AHA)
Baxter	American Nurses Association (ANA)
Berry Global	Association for Accessible Medicines
Bound Tree	Big City Emergency Managers
Cardinal Health	Biotechnology Innovation Organization (BIO)
Center for Applied Innovation	Health Industry Distributors Association (HIDA)
Clock Medical Supply	Healthcare Distribution Alliance (HDA)
Davis Polk & Wardwell	National Association of Manufacturers (NAM)
Draeger	National Emergency Management Association
Drive Medical	Pharmaceutical Research and Manufacturers of America (PhRMA)
Gemini Bio-Products	
General Electric	
Grainger	
HealthTrust Purchasing Group, LP	
Henry Schein	
Husco International	
ICU Medical	
Integrated MedCraft	
Marena Group	
Masimo	
McKesson	
Medline	
Medtronic	
Morris and Dickson	
Nephron Pharmaceuticals	
Northwell Health	
Owens and Minor	
Premier Inc.	
ResMed Corp.	
Saab USA	
Shawmut Corporation	
Siemens Healthineers	
Teleflex	
Thermo Fisher	
Thomas Scientific	

Vizient	
Vyaire	
Zoll Medical	

As of <u>January 15, 2021</u>, the "Meeting to Implement the Voluntary Agreement Participants" list was as follows (61 companies' total: 47 Participants and 14 Attendees):

Participants:	**Attendees:**
3M	Advanced Medical Technology Association
Amerisource Bergen	American Hospital Association (AHA)
Baxter	American Nurses Association (ANA)
Berry Global	Association for Accessible Medicines
Bound Tree	Big City Emergency Managers
Cardinal Health	Biotechnology Innovation Organization (BIO)
Center for Applied Innovation	Health Industry Distributors Association (HIDA)
Clock Medical Supply	Healthcare Distribution Alliance (HDA)
Concordance	Healthcare Ready
Draeger	International Association of Emergency Managers
Drive Medical	International Safety Equipment Association (ISEA)
Gemini Bio-Products	National Association of Manufacturers (NAM)
General Electric	National Emergency Management Association
Gentex	Pharmaceutical Research and Manufacturers of America (PhRMA)
Grainger	
HealthTrust Purchasing Group, LP	
Henry Schein	
Honeywell	
Husco International	
ICU Medical	
Integrated MedCraft	
Jabil Defense and Aerospace	
Marena Group	
Masimo	
McKesson	
Medline	
Medtronic	
Moldex	
Morris and Dickson	
MSA Safety	
Nephron Pharmaceuticals	
Northwell Health	
Owens and Minor	
Premier Inc.	
ResMed Corp.	

RPB Safety	
Saab USA	
SAS	
Shawmut Corporation	
Siemens Healthineers	
Stryker	
Teleflex	
Thermo Fisher	
Thomas Scientific	
Vizient	
Vyaire	
Zoll Medical	

Appendix C. Plan of Action

Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 Implemented under the Voluntary Agreement for the 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), developed a Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement), 85 FR 50035 (August 17, 2020). The Voluntary Agreement, which operates through a series of Plans of Action, maximizes the manufacture and efficient distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, as authorized by FEMA, and allocation and distribution of Critical Healthcare Resources.

This document establishes a Plan of Action (Plan) for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19. This Plan will be implemented under the Voluntary Agreement by several Sub-Committees:

A. Sub-Committee to Define COVID-19 PPE Requirements,
B. Sub-Committee for N-95 and other Medical Respirators,
C. Sub-Committee for Gloves,
D. Sub-Committee for Gowns, and
E. Sub-Committee for Eye and Facial Coverings.

FEMA may establish additional Sub-Committees under this Plan of Action, so long as:

A. The Sub-Committee addresses one specific and well-defined category of PPE; and
B. The Sub-Committee is recommended by the Sub-Committee to Define COVID-19 PPE Requirements.

The purpose of the Plan and the Sub-Committees is to maximize the manufacture and efficient distribution of selected types of critical PPE and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements including geographic and regional circumstances. The primary goal of the Plan is to create a mechanism to immediately meet exigent PPE requests anywhere in the Nation and to ensure that actions to support PPE stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential PPE recipients. When the requirements of the Plan are met, it affords Sub-Committee Participants defenses to civil and

criminal actions brought under the antitrust laws (or any similar law of any state) for actions taken within the scope of the Plan. The Plan is designed to foster a close working relationship among FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active supervision of FEMA.

1. 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 PPE is necessary for the national defense. This Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 is established under the Voluntary Agreement and establishes five Sub-Committees to oversee and implement the Plan. The Plan and Sub-Committees will optimize the manufacture and the efficient distribution of selected types of critical PPE and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements and taking into account geographic and regional circumstances for stabilization and reduction of COVID-19 exposure.

2. 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 (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 Plan is necessary for the national defense.

3. General Provisions

1) Definitions

a. Administrator

The FEMA Administrator is the Sponsor of the Voluntary 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 the Voluntary Agreement, including through the development and implementation of Plans of Action. 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 all Sub-Committees formed to carry out the Voluntary Agreement.

b. Agreement

The Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement)

c. Allocation

The process of determining and directing the relative distribution among one or more competing requests from End-Users for the same PPE. Through the Allocation process, FEMA – with participation from Sub-Committee Participants – will assess the actual needs of End-Users and determine how to divide the available and projected supply of PPE to minimize impacts to life, safety, and economic disruption associated with shortages of critical PPE. Allocation will take place only under Exigent Circumstances. FEMA retains decision-making authority for all Allocation under this Plan.

d. Attendees

Subject matter experts, invited by the Chairperson or a Sub-Committee Chairperson to attend meetings authorized under the Voluntary Agreement or this Plan of Action, to provide technical advice or to represent other government agencies or interested parties. Invitations to attendees will be extended as required for Committee or Sub-Committee meetings and deliberations.

e. Chairperson

FEMA senior executive(s), appointed by the Administrator, to chair the Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee). The Chairperson shall be responsible for the overall management and administration of the Committee, the Voluntary Agreement, and Plans of Action developed under the Voluntary Agreement while remaining under the supervision of 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 the Voluntary Agreement; appoint one or more co-Chairpersons to chair the Committee, and otherwise shall carry out all duties and responsibilities assigned to him. With the approval of the Administrator, the Chairperson may create one or more Sub-Committees, and may appoint one or more Sub-Committee Chairpersons to chair the Sub-Committees, as appropriate.

f. Committee

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under the Voluntary Agreement.

g. Competitively Sensitive Information

Competitively Sensitive Information that is shared pursuant to this Plan of Action may include any Document or other tangible thing or oral transmission that contains financial, business, commercial, scientific, technical, economic, or engineering information or data, including, but not limited to:

- financial statements and data,
- customer and supplier lists,
- price and other terms of sale to customers,

- sales records, projections and forecasts,
- inventory levels,
- capacity and capacity utilization,
- cost information,
- sourcing and procurement information,
- manufacturing and production information,
- delivery and shipping information,
- systems and data designs, and
- methods, techniques, processes, procedures, programs, codes, or similar information, whether tangible or intangible, and regardless of the method of storage, compilation, or recordation, if the owner thereof has taken reasonable measures to protect the information from disclosure to the public or competitors. These measures may be evidenced by marking or labeling the items as "competitively sensitive information" during submission to FEMA or in the Participant's customary and existing treatment of such information (regardless of labeling).

All Competitively Sensitive Information provided by a Sub-Committee Participant as described herein is deemed Competitively Sensitive Information, except for Information that:

(1) is published or has been made publicly available at the time of disclosure by the Sub-Committee Participant;
(2) was in the possession of, or was lawfully and readily available to, FEMA from another source at the time of disclosure without breaching any obligation of confidentiality applicable to the other source; or
(3) was independently developed or acquired without reference to or reliance upon the Sub-Committee Participant's Competitively Sensitive Information;

Where information deemed Competitively Sensitive Information is required to be disclosed by law, regulation, or court order, the "Competitively Sensitive" (or substantially similar) label will continue to attach to all information and portion(s) of documents that are not made public through the required disclosure.

h. Document

Any information, on paper or in electronic/audio/visual format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant and used or shared in the course of participation in the Voluntary Agreement or a subsequent Plan of Action.

i. End-User

This includes all direct and ancillary medical support including, but not limited to, hospitals, independent healthcare providers, nursing homes, medical laboratories, dental care providers, independent physician offices, first responders, alternate care facilities and the general public that reasonably represents the totality of the nation's professional or medical response to COVID-19. "End-User" may also include essential workers necessary to maintain or restore critical infrastructure operations, including but not limited to law enforcement, education, food and agriculture, energy, water and wastewater, and public

works personnel.

j. Exigent Circumstances

As determined by the Chairperson, the actual or forecasted shortage of a particular type or types of PPE which likely cannot be fulfilled via usual market mechanisms for an acute, critical time period, and where immediate and substantial harm is projected to occur from lack of intervention.

k. 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).

l. 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 the Voluntary Agreement, that has been specifically invited to participate in the Voluntary Agreement by the Chairperson, and that has applied and agreed to the terms of the Voluntary Agreement. "Participant" includes a corporate or non-corporate entity entering into the Voluntary 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 the Voluntary Agreement at any time during its effective period.

m. Personal Protective Equipment (PPE)

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.

n. Plan of Action (Plan)

This document. A documented method, pursuant to 50 U.S.C. 4558(b)(2), proposed by FEMA to implement a particular set of activities under the Voluntary Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

o. Plan of Action Agreement

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action as part of one or more Sub-Committees. Completing the Plan of Action Agreement confers responsibilities on the Participant consistent with those articulated in the Plan of Action and affords Participants a defense against antitrust claims

under section 708 for actions taken to develop or carry out the Plan of Action and the appropriate Sub-Committee(s), as described in Section IV below.

p. Representatives

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other federal agencies with equities in this Plan, 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.

q. Sub-Committee

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

r. Sub-Committee Chairperson

FEMA official, appointed by the Chairperson, to chair a Sub-Committee to implement a Plan of Action. The Sub-Committee Chairperson shall be responsible for the overall management and administration of the Sub-Committee in furtherance of this Plan of Action while remaining under the supervision of the Administrator and the Chairperson.

s. Sub-Committee Members

Collectively the Sub-Committee Chairperson(s), Representatives, and Sub-Committee Participants. Jointly responsible developing and executing this Plan.

t. Sub-Committee Participant

A subset of Participants of the Committee, that have been specifically invited to participate in a Sub-Committee by the Sub-Committee Chairperson, and that have applied and agreed to the terms of this Plan and signed the Plan of Action Agreement. The Sub-Committee Chairperson may invite Participants in the Committee to join a Sub-Committee as a Sub-Committee Participant at any time during the Plan's effective period.

2) Plan of Action Participation

This Plan will be carried out by a subset of the Participants in the Voluntary Agreement through several Sub-Committees:

a. Sub-Committee to Define COVID-19 PPE Requirements;
b. Sub-Committee for N-95 and other Medical Respirators;
c. Sub-Committee for Gloves;
d. Sub-Committee for Gowns; and
e. Sub-Committee for Eye and Facial Coverings.

FEMA may establish additional Sub-Committees under this Plan of Action, so long as:

a. The Sub-Committee addresses one specific and well-defined category of PPE; and
b. The Sub-Committee is recommended by the Sub-Committee to Define COVID-19 PPE Requirements.

Each Sub-Committee will consist of the (1) Sub-Committee Chairperson(s), (2) Representatives from FEMA, HHS, the Department of Justice (DOJ), and other federal agencies with equities in this Plan, and (3) Sub-Committee Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Plan and have signed the Plan of Action Agreement. The Chairperson shall invite Sub-Committee Participants who, in his or her determination, are reasonably representative of the appropriate industry or segment of such industry. Other Attendees – invited by the Sub-Committee 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 Sub-Committee meetings. The naming of these Sub-Committees does not commit the Administrator to creating them unless and until circumstances dictate.

3) Effective Date and Duration of Participation

This Plan is effective immediately upon satisfaction of the requirements of DPA section 708(f)(1). This Plan shall remain in effect until terminated in accordance with 44 CFR 332.4. It shall be effective for no more than five (5) years from August 17, 2020, when the requirements of DPA section 708(f)(1) were satisfied for the Voluntary Agreement, 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 Plan until it is activated, as described in Section III(E), below.

4) Withdrawal

Participation in the Plan is voluntary, as is the acceptance of most obligations under the Plan. Sub-Committee Participants may withdraw from this Plan or from an individual Sub-Committee at any point, subject to the fulfillment of obligations previously agreed upon by the Participant prior to the date of withdrawal. Note that the obligations outlined in V.B regarding information management and associated responsibilities apply once a party has shared or received information through a Sub-Committee and remain in place after the party's withdrawal from the Sub-Committee or Plan. If a Sub-Committee Participant indicates an intent to withdraw from the Plan due to a modification or amendment of the Plan (described below), the Sub-Committee Participant will not be required to perform actions directed by that modification or amendment. *Withdrawal from the Plan will automatically trigger withdrawal from all Sub-Committees; however, a Participant may withdraw from a Sub-Committee without also withdrawing from the Plan or other Sub-Committees*. To withdraw from the Plan or from an individual Sub-Committee, a Participant must provide written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that Sub-Committee Participant's withdrawal specifying the scope of withdrawal. Following receipt of such notice, the Administrator will inform the other Sub-Committee Participants of the date and the scope of the withdrawal.

Upon the effective date of the withdrawal from the Plan, the Sub-Committee Participant must cease all activities under the Plan. Upon the effective date of the withdrawal from one or more Sub-Committee(s), the Sub-Committee Participant

must cease all activities under the Plan that pertain to the withdrawn Sub-Committee(s).

5) Plan of Action Activation and Deactivation

The Administrator, in consultation with the Chairperson and Sub-Committee Chairperson, will invite a select group of Participants in the Voluntary Agreement to form the following Sub-Committees, which will be responsible for implementing this Plan:

a. Sub-Committee to Define COVID-19 PPE Requirements;
b. Sub-Committee for N-95 and other Medical Respirators;
c. Sub-Committee for Gloves;
d. Sub-Committee for Gowns; and
e. Sub-Committee for Eye and Facial Coverings.

FEMA may establish additional Sub-Committees under this Plan of Action, so long as:

a. The Sub-Committee addresses one specific and well-defined category of PPE; and
b. The Sub-Committee is recommended by the Sub-Committee to Define COVID-19 PPE Requirements.

This Plan will be activated for each invited Participant when the Participant executes a Plan of Action Agreement, and a Participant may not participate in a Sub-Committee until the Plan of Action Agreement is executed. Participants will be invited to join this Plan at the discretion of the Chairperson or the Sponsor to the Voluntary Agreement. Participants will be further invited to attend specific meetings of one or more Sub-Committees at the discretion of the Chairperson.

6) Rules and Regulations

Sub-Committee 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.

7) Modification and Amendment

The Administrator, after consultation with the Attorney General and the Chairman of the FTC, may terminate or modify, in writing, this Plan at any time. The Attorney General, after consultation with the Chairman of the FTC and the Administrator, may terminate or modify, in writing, this Plan at any time. Sub-Committee Participants may propose modifications or amendments to the Plan or to the Sub-Committees at any time.

Where possible, material modifications to the Plan or a Sub-Committee will be subject to a 30 calendar day delayed implementation and opportunity for notice and comment by Sub-Committee Participants to the Chairperson. This delayed implementation period may be

shortened or eliminated if the Administrator deems it necessary. The Administrator shall inform Sub-Committee Participants of modifications or amendments to the Plan or to the Sub-Committees as they are proposed and issued.

The Administrator, after consultation with the Attorney General and the Chairman of the FTC, may remove Sub-Committee Participants from the Plan or from a Sub-Committee at any time. The Attorney General, after consultation with the Chairman of the FTC and the Administrator, may remove Sub-Committee Participants from this Plan or from a Sub-Committee at any time. If a Participant is removed from the Plan or from a Sub-Committee, the Participant may request written notice of the reasons for removal from the Chairperson, who shall provide such notice in a reasonable time period.

8) Expenses

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

9) Record Keeping

Each Sub-Committee 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 Plan. Each Sub-Committee Participant shall maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Sub-Committee Participants or with any other member of the Sub-Committee, including drafts, related to the carrying out of this Plan or incorporating data or information received in the course of carrying out this Plan. Each Sub-Committee 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.

4. Antitrust Defense

Under the provisions of DPA subsection 708(j), each Sub-Committee Participant in this Plan 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 Plan, that such action was taken by the Sub-Committee Participant in the course of developing or carrying out this Plan, that the Sub-Committee Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Sub-Committee Participant acted in accordance with the terms of the Voluntary Agreement and this Plan. Except in the case of actions taken to develop this

Plan, this defense shall be available only to the extent the Sub-Committee Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Plan and within the scope of the appropriate Sub-Committee(s), including being taken at the direction and under the active supervision of FEMA.

This defense shall not apply to any actions taken after the termination of this Plan. Immediately upon modification of this Plan, no defense to antitrust claims under Section 708 shall be available to any subsequent action that is beyond the scope of the modified Plan. The Sub-Committee 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.

5. Terms and Conditions

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

1) Plan of Action Execution

This Plan will be used to support the following objectives to respond to a Pandemic by maximizing the manufacture and efficient distribution of selected types of critical PPE and creating a prioritization protocol for End-Users based upon their demonstrated or projected requirements and taking into account geographic and regional circumstances. Each Sub-Committee will undertake the following Objectives for the PPE item(s) within its area of jurisdiction.

a. Objectives

(1) Optimize the timely production of sufficient quantities of PPE to reduce loss of life and transmission of the COVID-19 virus.
(2) Ensure PPE is distributed effectively across the whole community nationally based on risk.
(3) Balance restoration and maintenance of the nation’s stockpile of PPE with near-term requirements.
(4) Establish a process for FEMA Allocation of PPE nationwide.
(5) Ensure ongoing competition in the manufacture and distribution of PPE to the greatest extent possible under the DPA.

b. Actions

Sub-Committee Participants may be asked to support these objectives by taking the following specific actions:

(1) Assist the Chairperson in identifying which types of critical PPE should be included within each Sub-Committee. Identification will be based upon each item's importance to the national response to COVID-19 and whether it can be reasonably inferred, based upon the best evidence available, that that current and projected supply measured against current and projected demand may not adequately meet the PPE requirements to all identified End-Users or regional or geographic areas of the country as result of measures taken to respond to COVID-19.

(2) Provide input to the Chairperson in creating a prioritized list of PPE End-Users by categories for each type of critical PPE identified by each Sub-Committee and ascertaining the relative demand and supply of PPE among and within those End User categories. Prioritization shall be decided by the Chairperson, based upon each item's importance, reflecting the consensus views of the Sub-Committee Members that it represents the most effective way to save lives and prevent the transmission of the COVID-19 virus. This list may be updated throughout the life of the Plan of Action based upon either short term or long-term demands. These categories should be considered holistically in terms of the Whole-of-Nation response to COVID-19.

(3) Evaluate the domestic supply of PPE and identify when the expansion of the domestic manufacture of PPE may be necessary, as directed and decided by the Chairperson.

(4) Provide information, assist, and validate, as necessary as decided by the Chairperson, demand projections for PPE.

(5) Create a process for and collaborate in the evaluation of competing claims for PPE from End-Users.

(6) Prepare a general strategy to accomplish the activities listed in V(A)(2)(7) below regarding activities in Exigent Circumstances consistent with the decisions made by the Chairperson.

(7) In Exigent Circumstances, with review and concurrence in all possible instances by DOJ in consultation with FTC:

- Facilitate maximum availability of PPE to the nation or particular geographies by deconflicting overlapping demands from the collective Participants' customer base, as directed and decided by the Chairperson.
- Facilitate maximum availability of PPE to the nation or particular geographies by deconflicting overlapping supply chain demands placed upon Members, as directed and decided by the Chairperson.
- Facilitate the efficient distribution of PPE by deconflicting overlapping

distribution chain activities of Members, as directed and decided by the Chairperson.

- Create a process for and collaborate in the Allocation of PPE nationwide or in particular geographies consistent with the decisions made by the Chairperson.
- Create a process for and collaborate in meeting any other exigent requirements throughout the nation or particular geographies consistent with the overall strategy prepared by this Sub-Committee

(8) Provide data and information necessary to validate the efforts of the Sub-Committee including the actual and planned amounts of PPE to be distributed throughout the Nation, as determined by the Chairperson.

(9) Provide feedback to the Sub-Committee on the outcomes of the collective efforts of the Sub-Committee Members and any impediments or bottlenecks.

(10) Advise the Chairperson whether additional Participants or Attendees should be invited to join this Plan of Action and Sub-Committee.

(11) Carry out other activities regarding critical PPE as identified by Sub-Committees under this Plan as determined and directed by the Chairperson necessary to address the COVID-19 virus' direct threat to the national defense, where such activities have been reviewed and approved by DOJ and FTC and received concurrence from Sub-Committee members.

2) Information Management and Responsibilities

FEMA will request only that data and information from Sub-Committee Participants that is necessary to meet the objectives of the Plan and consistent with the scope of the relevant Sub-Committees. Upon signing a Plan of Action Agreement for this Plan, FEMA requests that Participants endeavor to cooperate with diligence and speed, and to the extent permissible under this Plan, and share with FEMA data and information necessary to meet the objectives of this Plan.

Sub-Committee Participants agree to share with FEMA the following data with diligence and speed, to the extent permissible under this Plan, and abide by the following guidelines, where feasible and consistent with the data that is owned by each Sub-Committee Participant:

a. In general, Participants will not be asked to share Competitively Sensitive Information directly with other Participants.

b. FEMA will only request direct sharing of Competitively Sensitive Information among Participants during Exigent Circumstances where there is a mission critical need or timeline such that sharing only through FEMA is impractical or threatens the outcome of the Plan or Sub-Committee action. Such requests, if made, will be

only among Participants whose participation is necessary to meet the objectives of the Plan, will be limited in scope to the greatest extent possible, and will be shared only pursuant to safeguards subject to prior review and audit by DOJ and FTC. Direct sharing of Competitively Sensitive Information with other Participants will be limited in scope and circumstances to the greatest extent possible. Participants may not share Competitively Sensitive Information directly with other Participants unless specifically requested by FEMA, in consultation with DOJ and FTC. All Competitively Sensitive Information delivered to FEMA or to another Sub-Committee Participant shall be delivered by secure means, for example, password-protected or encrypted electronic files or drives with the password/key delivered by separate communication or method or via upload to an appropriately secure web portal as directed by FEMA. All data delivered to the web portal designated by FEMA is deemed to be Competitively Sensitive Information.

c. To allow FEMA to identify and appropriately protect documents containing Competitively Sensitive Information by the Sub-Committee Participant providing the documents, the Sub-Committee Participant will make good faith efforts to designate any Competitively Sensitive Information by placing restrictive markings on documents and things considered to be competitively sensitive, the restrictive markings being sufficiently clear in wording and visibility to indicate the restricted nature of the data. The Sub-Committee Participant will identify Competitively Sensitive Information that is disclosed verbally by oral warning. Information designated as competitively sensitive will, to the extent allowed by law, be presumed to constitute trade secrets, or commercial or financial information, and be provided by the Sub-Committee Participant to FEMA with the expectation that it will be kept confidential by both parties, as such terms are understood in accordance with 5 U.S.C. § 552(b)(4) of the Freedom of Information Act and federal judicial interpretations of this statute. FEMA agrees that to the extent any information designated as competitively sensitive by a Sub-Committee Participant is responsive to a request for disclosure under the Freedom of Information Act, FEMA will consult with the Sub-Committee Participant and afford the Participant ten (10) working days to object to any disclosure by FEMA.

d. FEMA will make good faith efforts to appropriately recognize unmarked Documents containing Competitively Sensitive Information as Competitively Sensitive Information. However, FEMA cannot guarantee that all unmarked Documents will be recognized as being Competitively Sensitive Information and protected from disclosure to third parties. If the unmarked Documents have not been disclosed without restriction outside of FEMA, the Sub-Committee Participant may retroactively request to have appropriate designations placed on the Documents. If the unmarked Documents have been disclosed without restriction outside of FEMA, FEMA will, to the extent practicable, remove any requested information from public forums controlled by FEMA and will work promptly to request that a receiving party return or destroy disclosed unmarked Documents if requested by the Sub-Committee Participant.

e. Competitively Sensitive Information may be used by FEMA, alone or in combination with additional information, including Documents and Competitively Sensitive Information received from third parties, to support FEMA's implementation of this Plan of Action as determined by the Chairperson. In all situations, FEMA will aggregate and anonymize Competitively Sensitive Information to the greatest extent possible to protect the interests retained by the owners of the data while still allowing the objectives of the Plan of Action and Sub-Committee to be achieved. To the greatest extent possible, such aggregation will render the competitively sensitive nature of the Competitively Sensitive Information of the Sub-Committee Participant no longer recognizable in a commercially sensitive manner, and without sufficient information to enable, by inference or otherwise, attribution to Sub-Committee Participant or its affiliates (as clearly identified and disclosed to FEMA). Any disclosure of Competitively Sensitive Information by FEMA, within or outside a Sub-Committee, will be subject to review and approval by DOJ and FTC.

f. Except as otherwise expressly permitted by applicable federal law, FEMA shall not disclose any Competitively Sensitive Information or use any Competitively Sensitive Information for any purpose other than in connection with the purposes of this Plan of Action, and FEMA will not sell any Competitively Sensitive Information of any Sub-Committee Participant.

g. Except as described below, FEMA may disclose Competitively Sensitive Information only to its employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors). Any individual with access to Competitively Sensitive Information will be expected to comply with the terms of this Plan of Action.

(1) Information Sharing within the Sub-Committee: FEMA may share Competitively Sensitive Information with Sub-Committee Participants and Federal Representatives of the Plan of Action, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) where there is a need to know and where disclosure is reasonably necessary in furtherance of implementing the Plan of Action. FEMA will aggregate and anonymize data prior to sharing with the Sub-Committee Participants to the greatest extent possible while still allowing the objectives of the Plan of Action to be achieved, and will not share data – particularly to competitors of the submitter – prior to consultation with and approval by the DOJ and FTC.

(a) Sub-Committee Participants, when providing Competitively Sensitive Information to FEMA, may request that this Information not be shared with other Sub-Committee Participants. Where these requests are made in good faith and are reasonable in nature, FEMA will respect these requests to the greatest extent possible and will consult the owner of the data prior to any release made to Sub-Committee Participants.

(2) Restricted Reports. FEMA may communicate Competitively Sensitive Information

to appropriate government officials through Restricted Reports. The information contained in Restricted Reports shall be aggregated and anonymized to the greatest extent possible, while recognizing that these officials may need a certain amount of granularity and specificity of information to appropriately respond to COVID-19. FEMA will aim to aggregate data to the County level and will not share Restricted Reports prior to consultation and approval from the DOJ and FTC. FEMA may disclose Restricted Reports to relevant White House and Administration officials and State Governors, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) who have a need to know and to whom such disclosure is reasonably necessary solely in furtherance of the implementation of this Plan of Action. FEMA shall take appropriate action (by instructions, agreement, or otherwise) to ensure that receiving parties comply with all data-sharing confidentiality and obligations under this Plan of Action as if such persons or entities had been parties to this Plan of Action.

(3) Public Reports. FEMA may share information with the public through Public Reports. Data contained in Public Reports shall be fully aggregated and anonymized. Public Reports shall be aggregated to at least a state level and may be publicly disclosed after consultation and approval from the DOJ and FTC.

h. Where possible and not obviated by Exigent Circumstances, FEMA will notify Sub-Committee Participants prior to the release of any Competitively Sensitive Information that has not been fully aggregated and anonymized. In consultation with DOJ and FTC, FEMA will consider any good-faith requests made by Sub-Committee members to hold the release of data or requests for further aggregation or anonymization. In general, FEMA will not provide notification prior to the release of Public Reports, under the presumption that the data in these reports has already been fully anonymized and de-identified.

i. Any party receiving Competitively Sensitive Information through this Plan shall use such information solely for the purposes outlined in the Plan and take steps, such as imposing previously approved firewalls or tracking usage, to prevent misuse of the information. Disclosure and use of Competitively Sensitive Information will be limited to the greatest extent possible, and any party receiving Competitively Sensitive Information shall follow the procedures outlined in paragraph 7 above.

j. At the conclusion of a Participant's involvement in a Plan – due to the deactivation of the Plan 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. This sequestration shall 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.

3) Oversight

Each Sub-Committee Chairperson is responsible for ensuring that 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 Plan, including activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chairman, or their delegates may attend Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Plan. DOJ or FTC Representatives may request and review any proposed action by the Sub-Committee or Sub-Committee Participants undertaken pursuant to this Plan, 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 Sub-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.

6. Establishment of the Sub-Committees

This Plan establishes Sub-Committees to implement the Plan to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 to provide the Federal Government and the Participants a forum to maximize the manufacture and efficient distribution of selected types of critical PPE and to create a prioritization protocol based upon identified types of PPE End-Users and their demonstrated or projected requirements, and demonstrated or projected geographic and regional areas of need. The outcome should include a framework to expeditiously meet any PPE needs in Exigent Circumstances anywhere in the Nation, and to ensure that actions to support PPE stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential PPE recipients. A Sub-Committee Chairperson designated by the Chairperson will convene and preside over each Sub-Committee. Sub-Committees 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 Plan.

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

To the extent necessary to respond to the Pandemic, only at the explicit direction of a Sub-Committee Chairperson, and subject to the provisions of Section V(B), Sub-Committee Members may be asked to provide technical advice, share information, help identify and validate places and resources of the greatest need, help project future manufacturing and distribution demands, assist in identifying and resolving the allocation of scarce resources amongst all necessary public and private sector domestic needs under Exigent Circumstances, and take any other necessary actions to maximize the timely manufacture and distribution of PPE as determined necessary by FEMA to respond to the Pandemic. A Sub-Committee Chairperson or his or her designee, at the Sub-Committee Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum efficiency and effectiveness in the use of Sub-Committee Member's resources. All Sub-Committee Participants will be invited to open Sub-Committee meetings. For selected Sub-Committee meetings, attendance may be limited to designated Sub-Committee Participants to meet specific operational requirements, as determined by FEMA.

Each Sub-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 Plan of Action. Additionally, each Sub-Committee 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. A Sub-Committee 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 (10) days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Sub-Committee 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 Sub-Committee Participants. The Chairperson shall take necessary actions to protect from public disclosure any data discussed with or obtained from Sub-Committee Participants which a Sub-Committee 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.

7. Application and Agreement

The Sub-Committee Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) under the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and to become a Participant in one or more Sub-Committees established by this Plan. This Plan will be published in the *Federal Register*. This Plan is authorized under section 708 of the Defense Production Act of 1950, as amended.

Regulations governing the Voluntary Agreement for the Manufacture and Distribution for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and all subsequent Plans of Action appear at 44 CFR part 332. The applicant, as a Sub-Committee 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 Plan.

8. Assignment

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

This document was published to the Federal Register in this location:

- ***Voluntary Agreement:*** *https://www.federalregister.gov/documents/2020/08/17/2020-18005/voluntary-agreement-under-section-708-of-the-defense-production-act-manufacture-and-distribution-of*
- ***Supporting Documentation:*** *https://www.regulations.gov/docket/FEMA-2020-0016/document*

Appendix D. Participants in the PPE Plan of Action

As of January 15, 2021, Plan of Action to Establish a National Strategy for the Manufacture, Allocation and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 Participants list (28 companies' total: 17 Participants and 11 Attendees):

Participants:	**Attendees:**
3M	Advanced Medical Technology Association
Bound Tree	American Hospital Association (AHA)
Cardinal Health	American Nurses Association (ANA)
Center for Applied Innovation	Big City Emergency Managers
Concordance	Health Industry Distributors Association (HIDA)
Grainger	Healthcare Distribution Alliance (HDA)
Henry Schein	Healthcare Ready
Honeywell	International Association of Emergency Managers
Husco International	International Safety Equipment Association (ISEA)
Jabil Defense and Aerospace	National Association of Manufacturers (NAM)
McKesson	National Emergency Management Association
Medline	
Northwell Health	
Owens and Minor	
Premier Inc.	
Stryker	
Vizient	

Appendix E. Acronyms

COVID-19	Coronavirus Disease 2019
CY	Calendar Year
DHS	Department of Homeland Security
DOC	Department of Commerce
DOD	Department of Defense
DOE	Department of Energy
DOJ	Department of Justice
DOT	Department of Transportation
DPA	Defense Production Act of 1950
E.O.	Executive Order
FEMA	Federal Emergency Management Agency
FTC	Federal Trade Commission
HHS	Department of Health and Human Services
OB3I	FEMA's Office of Business, Industry and Infrastructure Integration
PPE	Personal Protective Equipment