



Healthcare Distribution Alliance

PATIENTS MOVE US.

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<http://www.regulations.gov>; Docket ID: FEMA-2020-0016

Pete Gaynor
Administrator
Federal Emergency Management Agency
500 C Street SW
Washington, DC 20472-3184
FEMA-DPA@fema.dhs.gov

RE: Meeting to Develop Pandemic Response; Voluntary Agreement, Dkt. No. FEMA-2020-0016, 85 Fed. Reg. 28031 (May 12, 2020)

Dear Administrator Gaynor:

On behalf of the Healthcare Distribution Alliance (HDA) and our members, I appreciate the opportunity to provide comments regarding pandemic response and the Federal Emergency Management Agency's (FEMA) draft voluntary agreement. We are encouraged by FEMA's recognition of the value of partnering with supply chain experts from the private sector and we look forward to adding our voice to this process.

HDA represents the nation's primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned, and small businesses. HDA member companies deliver nine million healthcare products to more than 180,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

Because over 92 percent of medications shipped in the United States arrive at their dispensing location because of an HDA member company, HDA members have played a critical role in the nation's COVID-19 response. HDA's 36 distributor members are committed to assisting the country and our frontline healthcare providers during the pandemic. Pharmaceutical wholesale distributors are working around-the-clock to increase medical capacity and enhance our national

supply of critical medications and supplies required to fight this pandemic, protect our frontline care providers, and enable treatment for patients.

Pharmaceutical distributors respond to evolving customer needs by working closely with manufacturers, sourcing organizations, industry partners and government agencies to anticipate changes in demand, mitigate disruptions and ensure that healthcare providers everywhere have access to available medicines. Distributors consider a range of data points to meet the constantly changing inventory needs of healthcare providers. This includes internally maintained historical sales and distribution data, information from federal and state governments, and data from acutely impacted areas and several third-party healthcare organizations. During a crisis such as the current pandemic, distributor historical data may be updated frequently, and distributors rely on all available sources of dynamic information.

Working as the conduit between manufacturers and healthcare providers, America's pharmaceutical distributors are in the business of finding the safest, most secure, and most efficient ways to swiftly deliver medicines to healthcare providers and the patients in their care. This is our members' core expertise and it is especially during public health crises that distributors play a vital role in emergency response efforts.

We commend FEMA and the White House Task Force for leading the Whole-of-America response to the COVID-19 pandemic and for coordinating deployment of billions of essential medicines, personal protective equipment (PPE), and other resources during the past several months. We support FEMA's efforts to consider establishing voluntary agreements with private sector stakeholders to enhance COVID-19 response. With the very short comment period provided and the limited time it has afforded for consultation with our members, we offer the following suggestions for your consideration:

- HDA supports the formation of an advisory committee and encourages FEMA to include a broad cross section of the industry. We also suggest, when forming the *Committee for the Distribution of Medical Resources Necessary to Respond to a Pandemic* (the "Committee"), that FEMA include distributor representatives and consider the expertise of both large public companies and smaller regional and specialty firms. While we acknowledge that larger companies may have, in turn, larger networks, we also laud the value of independent distributors who have valuable logistics expertise and unique connections in their regions and communities.
- Building upon the comments provided at the public meeting on May 21, 2020, we believe that a voluntary agreement should be available to all interested manufacturers, distributors and suppliers. In the case of wholesale distributors, capabilities, customer base, and geographic reach vary widely, with independent, smaller, regional and specialty

firms often reaching healthcare providers that larger companies do not service. Any company of good standing prepared to partner with FEMA, manufacturers, and healthcare providers should, in our view, be eligible.

- We agree with the suggestion made at the May 21, 2020 meeting that trade associations be considered as potential signatories as well. Trade associations are subject matter experts and could make meaningful contributions to supply chain understanding. In addition, trade associations are experienced in gathering confidential commercial data from their members, aggregating, and anonymizing that data, and sharing that information to improve insights.
- To that end, we recommend a potential restructuring of the proposed process for participation. Rather than requiring all potential participants to sign voluntary agreements based on the current draft, which is broad in scope, we suggest instead that FEMA adopt a stepwise plan. Interested relevant parties could “sign up” or otherwise agree to participate in a broader agreement to engage in the first step, including the proposed committee structure, thereby allowing FEMA to draw on a wide range of expertise and resources to develop its course of action. In the second step of the process, FEMA could enter into more detailed voluntary agreements with those entities positioned to provide specific deliverables. For instance, a pharmaceutical distributor could participate in the first step, but based on the product categories determined necessary for ultimate patient level distribution, may determine that it is unequipped to enter the second, more specific phase. An approach such as this would also provide a beneficial model for trade association engagement by facilitating the involvement of subject matter experts in the discussion phase but also making clear that those organizations would not be actually providing goods and services under the terms of the agreement. This process would also give entities more time to determine necessary contract terms, realistic capabilities and would enable the agency to provide more clarity based on lessons learned during the committee process.
- FEMA requested comments on the definitions in the proposed Voluntary Agreement draft. We note that, in the definition of “Critical Healthcare Resources” includes “pharmaceuticals” and “personal protective equipment” (PPE) but does not define “medical devices.” We suggest that FEMA add this definition to the Voluntary Agreement. Additionally, “Point of Care” is defined to include “Acute Care, First Responders, Nursing Homes, Private Hospitals, Public Hospitals and Veterans Administration Hospitals.” We suggest broadening this definition to include other healthcare providers, including, but not limited to physician and dentist offices, rehabilitation facilities, and clinics.
- Similarly, we believe that Section III.H. Expenses may need to be clarified. The section provides that “All expenses, administrative or otherwise, incurred by Participants

associated with participation in this Agreement shall be borne exclusively by the Participants.” We are concerned that this language does not seem to allow any owner of critical healthcare resources to sell them (whether to the government or to a healthcare provider) or for a distributor to charge for its distribution of those critical healthcare resources. We do not believe that it is the intent for all goods and services provided under the Voluntary Agreement to be donated. If this is the case, we recommend clarification.

- We strongly support robust antitrust protection for the Participants when undertaking activity under and pursuant to the Voluntary Agreement. HDA asks that FEMA carefully articulate this critical antitrust defense with the aid of the Federal Trade Commission (FTC) and Department of Justice (DOJ). We emphasize that there is no need to overly complicate this analysis. The DOJ and FTC have provided ample reasoning as to why the type of conduct anticipated under the Voluntary Agreement does not violate antitrust laws and also enjoys immunity under antitrust laws.
 - As DOJ articulated in its recently issued Business Review Letters (See [here](#) and [here](#)), the Participants’ collaborations to aid the government’s response to COVID-19 do not raise antitrust concerns. The proposed conduct is limited in scope and duration, is necessary to respond to COVID-19-related scarcity and meet urgent patient needs, and the procompetitive aspects of actions under Voluntary Agreement would far outweigh any theoretical harm.
 - Additionally, as the FTC and DOJ stated in the [Joint Antitrust Statement on COVID-19](#), the antitrust laws generally permit, under the Noerr-Pennington doctrine, private lobbying addressed to the use of federal emergency authority, including private industry meetings with the federal government to discuss strategies on responding to COVID-19. The efforts of Participants to influence FEMA’s, HHS’s, or another governmental agencies’ decisions regarding the U.S. Government’s policy of expediting health and medical resources in response to COVID-19 would likely be covered by Noerr-Pennington immunity. See DOJ Business Review Letters [here](#) and [here](#).
 - Section IV. Antitrust Defense, states that “This defense shall be available only if, and only to the extent that the Participants asserting it demonstrate that, the action, which includes a discussion or agreement, was within the scope of this Agreement and taken at the direction of FEMA and with appropriate FEMA oversight and approval.” Given that successful invocation of the antitrust defense requires that any action be taken with appropriate FEMA oversight and approval, we believe that the effectiveness of the Voluntary Agreement arrangement could be hindered if all actions must also be “taken at the direction of FEMA.” It seems impractical for

every action and decision that signatory undertakes must be done at the direction of FEMA and suggest this clause of the Voluntary Agreement be modified or omitted.

- Sections V. B. and E. refer to “manufacturing lines of effort” and we are unsure what this term is intended to cover.
- Section V. C. refers to the need to “validate” critical healthcare resource requirements. We are uncertain what “validate” means in this context.
- Section V.F., Joint Allocation of Critical Healthcare Resources, states that “When directed by FEMA and under FEMA’s supervision, members will collaborate in the voluntary Participant allocation of Critical Healthcare Resources nationwide.” It is not clear whether, under this provision, it is intended that FEMA would direct where healthcare resources are to be distributed or whether the participants make these important determinations.
- Sections V. A-D all require participant to share information “to the extent necessary.” We are uncertain from this proposed language who determines if information sharing is necessary and how it is determined that a participant has shared sufficient information.
- Coordination between the public and private sector is essential to effectively addressing challenges stemming from any declared state of emergency. To further facilitate uninterrupted access to the pharmaceutical and healthcare products HDA members provide, we encourage seamless communication and interagency collaboration to identify and minimize inefficiencies and gaps in preparedness and response, as well as provide guidance to the industry.
- As part of any agreements with the private sector, HDA recommends that the federal government provide detailed guidance to pharmaceutical distributors on how essential treatments, vaccines and supplies should be distributed during this declared state of emergency. It is critical that the federal and state authorities work together to designate priority populations, localities and types of facilities and communicate that information to the supply chain to ensure that as products are approved and manufactured, decisions and plans for distribution can be made.
- As COVID-19 treatments and vaccines are developed, distributors are prepared to ensure rapid patient access. However, significant guidance from federal and state governments would be very useful in designating healthcare providers that should be prioritized. We stand prepared to maximize the efficiencies of the existing private-sector distribution system to support response efforts to deliver treatments and vaccines to where they are

most needed. This is particularly important when a new treatment or vaccine is first entering the marketplace. Distributors have significant experience in launching new medicines and can be integral to ensuring:

- Inventories are pre-positioned in the supply chain to help facilitate ready access to providers;
- Drugs are available to providers as expeditiously as possible;
- Treatments and vaccines can reach facilities designated under each state's emergency preparedness plan; and,
- Distribution plans comply with existing federal and state regulations.

HDA understands that having accurate and timely information about the availability of supplies and medicines is vital during a state of emergency. HDA members are committed to working closely with federal and state governments to share information about the availability of essential medicines.

Strengthening communication between federal and state agencies and the pharmaceutical supply chain is imperative to maintaining and leveraging existing distribution channels and appropriately managing distribution of medical products during a declared state of emergency.

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HDA and its members are committed to working with FEMA, as well as other policymakers, regulators and supply chain stakeholders to tackle complex drug supply issues and ensure the availability of safe and effective drugs for the healthcare providers and patients who need them. HDA members are the supply chain experts needed to ensure the nation's pharmaceutical supply chain remains secure even in a time of crisis, while preserving access to essential products where and when they are needed.

We look forward to participating in this effort and stand ready as a resource for the Agency during this critical time for our nation.

Sincerely,



Elizabeth A. Gallenagh
Senior Vice President, Government Affairs and General Counsel