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AdvaMed
Advanced Medical Technology Association

December 11, 2020

TO: State Vaccine Allocation Authorities

Subject: Vaccine Allocation and Medical Technology Supply Chain Workers

We respectfully request that the state consider certain aspects of the medical device industry workforce in the development of vaccine allocation decisions. Specifically, our workers that perform critical functions alongside health care professionals on the front lines, including clinical representatives, technicians or others, should be included in Phase 1a based on their direct risk of exposure and to ensure continuity of patient care throughout the health care system. Additionally, "essential workers" throughout the medical product supply chain (suppliers, manufacturers, distribution, technicians, servicers) should be included in Phase 1b or other appropriate phase with other critical manufacturing essential workers.

As we move closer towards the approval of a COVID-19 vaccine, there must be a transparent and equitable plan for how patients access vaccinations and how that priority is determined. AdvaMed endorses the foundational principles utilized in the National Academies of Sciences, Engineering, and Medicine Framework for Equitable Allocation of COVID-19 Vaccine ("NAS Framework")—the maximization of benefits, equal regard, mitigation of health inequities, fairness, evidence-based decision-making, and transparency.[1] We also strongly support the recommended prioritization schema based on the four identified risk-based allocation criteria—the risk of acquiring infection, risk of severe morbidity and mortality, risk of negative social impact, and risk of transmitting the disease to others.[2]

As the state evaluates and develops COVID-19 vaccine allocation plans, AdvaMed would be grateful for guidance concerning medical device industry clinical field and manufacturing personnel, who are recognized in the U.S. Department of Homeland Security Cybersecurity & Infrastructure Security Agency (CISA) Guidance[3] as essential critical infrastructure healthcare workers. More specifically, guidance on

1 National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine.* Washington, DC: The National Academies Press. https://doi.org/10.17226/25917.

2 *I.d.*

3 U.S. Department of Homeland Security Cybersecurity & Infrastructure Security Agency, *Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response Version 4.0,* Aug. 18, 2020, available at https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infra

determining and confirming eligibility for these essential workers to be vaccinated under appropriate allocation phases would help to ensure their health and safety as they endeavor to maintain patient access to needed technology.

Health Care Industry Representatives (HCIR) – Phase 1a

Medical device company representatives are also referred to as Health Care Industry Representatives ("HCIRs"). They are often required to be present in-patient care settings to provide technical support concerning the safe and effective application of surgical products and technologies.[4] To this end, hospitals across this country have continued to allow HCIRs access to their cath labs and operating rooms to further the effective treatment of their patients. In these settings they me at direct risk of exposure to patient's specimens, including blood, tissue and other biological materials. In addition to this technical assistance function, HCIRs "may be involved in the remote calibration or adjustment of medical devices (for example, pacemakers, laser technology) to the surgeons' and manufacturers' specifications."[5] Generally, HCIRs must meet certain hospital supplier credentialing requirements to access certain areas of a hospital at the request of a healthcare provider. These credentialing requirements include documentation of vaccinations (or titers showing immunity) for Influenza, Tetanus, Diphtheria, Pertussis, Measles, Mumps, Varicella, and Hepatitis B.[6] It is also worth noting that the *American National Standard for Supplier Credentialing in Healthcare* was recently updated to include appropriate Personal Protective Equipment (PPE) use in healthcare provider facilities and a new section concerning Novel Viruses/Communicable Illness.[7] HCIRs are not contractors of the hospital; instead, they are employed or retained by medical device companies. This dynamic may complicate a vaccine administrator's ability to identify and flag HCIRs for prioritized vaccine allocation or to determine and confirm whether an HCIR meets the eligibility requirements for a

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structure_Workers_FINAL%20AUG%2018v3.pdf (Under "Healthcare / Public Health," "Vendors and suppliers" and "workers at manufacturers" are specified:

> Vendors and suppliers (e.g. imaging, pharmacy, oxygen services, durable medical equipment, etc.).
>
> Workers at manufacturers (including biotechnology companies and those companies that have shifted production to medical supplies), materials and parts suppliers, technicians, logistics and warehouse operators, printers, packagers, distributors of medical products and equipment (including third party logistics providers, and those who test and repair), personal protective equipment (PPE), isolation barriers, medical gases, pharmaceuticals (including materials used in radioactive drugs), dietary supplements, commercial health products, blood and blood products, vaccines, testing materials, laboratory supplies, cleaning, sanitizing, disinfecting or sterilization supplies

4 See Association of periOperative Registered Nurses (AORN), Position Statement on the Role of the Health Care Industry Representative in Perioperative Settings, May 28, 2020, available at https://aornjournal.onlinelibrary.wiley.com/doi/full/10.1002/aorn.13065.

5 American College of Surgeons (ACS). Revised Statement on Health Care Industry Representatives in the Operating Room, October 1, 2016, available at https://www.facs.org/about-acs/statements/91-industry-reps-in-or.

6 *See* American National Standard for Supplier Credentialing in Healthcare, ANSI/NEMA SC 1-2019, Contents and Scope available at https://webstore.ansi.org/preview-pages/NEMA/preview_ANSI+NEMA+SC+1-2019.pdf

7 See MITA and C4UHC Press Release, available at https://www.medicalimaging.org/wp-content/uploads/2020/05/20.05.05-Final_MITA-Credentialing-Standard-Release-DRAFT.docx-CLEAN-002-copy-1.pdf

particular phase of vaccination.

With regard to high-risk health workers identified for allocation Phase 1a of the NAS Framework, AdvaMed endorses the NAS Consensus Study statement that "access should not be defined by professional title, but rather by an individual's actual risk of exposure to COVID-19."[8] Consistent with that approach, certain medical device company representatives/HCIRs have an exposure risk to COVID-19 positive patients or their tissues, cells, or biofluids during their work to provide technical support for, calibrate, service, or repair medical devices (including diagnostics). HCIRs required by health care facilities or their job requirements to wear respirators and eye/face protection due to SARS CoV-2 exposure risk should be included among the Phase 1a allocation for High-Risk Health Workers.

Some HCIRs support procedures/equipment/technology in the operating room or procedural suite and are required to be present during urgent, non-elective procedures (e.g., trauma, transplant, cardiac) and other medically necessary procedures (e.g., joint replacement). During the pandemic, hospitals have instituted additional COVID-19 access requirements for HCIRs. For example, some hospitals required HCIRs to undergo respirator fit testing and training so that HCIRs will be able to utilize hospital-issued respirators during procedures that these HCIRs support. During crisis capacity operations, some hospitals have required that HCIRs bring in their own respirators and other PPE for the procedures that they support, including gloves, gowns, and face shields. During the current PPE shortage, distributors of NIOSH-approved N95 respirators allocate nearly all of their supply to hospital purchasers. The best-case scenario for medical device manufacturers is to procure non-NIOSH-approved filtering facepieces that have FDA emergency use authorization for use as a respirator during this public health emergency. In these cases, although both the hospital staff and HCIR are in similar proximity to aerosol-generating procedures, some HCIRs do not have equivalent PPE relative to the hospital staff. This dynamic should elevate the prioritization of these HCIRs relative to other high-risk health workers who have access to NIOSH-approved PPE.

Medical Device Manufacturing/Distribution Personnel – Phase 1b

Medical device industry personnel that are physically involved in manufacturing and distributing medical devices and diagnostics should be included among the Phase 1b allocation for Critical Workers in High-Risk Settings. The specialized and environmentally sensitive nature of manufacturing medical devices limits the ability of medical device manufacturers to increase the physical distance between some

8 National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine*. (p. 107) Washington, DC: The National Academies Press. https://doi.org/10.17226/25917. ("The first phase includes a "jumpstart" phase: Phase 1a. Included in Phase 1a would be "frontline" health workers—health professionals who are involved in direct patient care, as well as those working in transport, environmental services, or other health care facility services—who risk exposure to bodily fluids or aerosols. Under conditions of such scarcity, access should not be defined by professional title, but rather by an individual's actual risk of exposure to COVID-19. The rationale for including "frontline" health workers in the first phase is manifold: their contact with patients with SARS-CoV-2 (despite the use of PPE, which can be limited in some settings); the fact that they work in an essential industry, but may be precluded from performing their professional duties if they are exposed or infected; and the reality that many such workers are potentially important nodes in onward transmission networks, given that many who are in low-wage jobs may also contribute to further transmission due to living in crowded, often multi-generational living situations where social distancing is unrealistic.")

manufacturing personnel. These are critical workers who are essential to manufacturing and distributing medical devices and diagnostics integral to the treatment of COVID-19 and other patients and are at substantially higher risk of exposure due to their inability to physically distance.

Identification of Worker Categories

Finally, we believe that an attestation by an HCIR's employer on company letterhead concerning the nature of their work and exposure risk should be sufficient to confirm eligibility for the HCIR for vaccination during Phase 1a. If additional documentation is required from the health care facilities that the HCIR supports, a centralized approach with a standard form or direction concerning the specified elements required of supporting documentation would greatly help to minimize the administrative burden on health care facilities and clinicians. For medical device industry manufacturing and distribution personnel, an employer attestation on company letterhead concerning the nature of the individual's work should be sufficient documentation to confirm vaccination eligibility during Phase 1b.

AdvaMed appreciates your consideration and looks forward to supporting the state to achieve a transparent and equitable allocation of COVID-19 vaccines. We would be pleased to discuss these issues in greater detail at your convenience. Please do not hesitate to contact us at fgreaves@advamed.org or mbhatt@advamed.org.