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December 9, 2020

**Michele Roberts**
Acting Assistant Secretary

Prevention and Community Health Division

Washington Department of Health

Dear Assistant Secretary Roberts,

Most of Washington’s nearly 40,000 life science employees are working safely from home. However, there are two specific groups of biotech and medical device employees who are either working with frontline medical workers or producing essential medical products that we feel should be priority recipients of COVID-19 vaccines. As the state plan for allocating COVID-19 vaccinations is formulated, Life Science Washington urges you to include these two groups of workers in the early phases of the allocation plan.

First, there are a small number of uniquely credentialed medical device workers—referred to as **Health Care Industry Representatives**—that work in hospitals alongside frontline healthcare workers (and often travel between hospitals) that we feel should be prioritized in the **Phase 1a** vaccine allocation.

Second, there is a **subset of essential biotech and medical device workers** that work in labs on COVID-related vaccines and therapeutics as well as workers involved with manufacturing essential medical supplies that we urge you to include in the **appropriate allocation for high-risk essential workers** (**either 1b or 2**).

Please find attached a more detailed discussion of these two specific groups of workers as well as suggested language that could be used to define these workers in a manner consistent with the recommendations from the CDC’s Advisory Council on Immunization Practices (ACIP).

We appreciate your consideration and look forward to supporting the state to further a transparent and equitable allocation of COVID-19 vaccines. We would be pleased to discuss these issues in greater detail with you at your convenience.

Sincerely,



Marc Cummings

Vice President, Public Policy & External Affairs

Enclosure: High Risk Essential Life Science Workers

**High Risk Essential Life Science Workers**

**Health Care Industry Representatives—**Phase 1a

***Health Care Industry Representatives (HCIR) perform critical functions alongside health care professionals on the front lines, including industry representatives, technicians or others who should be included in Phase 1a based on their risk of exposure and to ensure continuity of patient care throughout the health care system.***

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.[[1]](#footnote-1)  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.”[[2]](#footnote-2)  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.[[3]](#footnote-3) 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.[[4]](#footnote-4) 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 particular phase of vaccination.

With regard to high-risk health workers identified for allocation Phase 1a of the NAS Framework, we endorse 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.”[[5]](#footnote-5)  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.

Importantly, HCIRs generally work across multiple health care facilities. Some HCIRs cover numerous hospital systems in a region and support procedures in multiple institutions per day. Vaccinating these HCIRs during Phase 1a would decrease the risk for these HCIRs to become vectors between institutions.

**Subset of essential biotech and medical device workers—**Phase1b or Phase 2 allocation for high-risk essential workers

There are two groups of essential biotech and medical device workers that should be included in the allocation for high-risk essential workers:

1. ***Biotechnology and medical research workers, including laboratory personnel, that perform critical clinical, biomedical and other research, development, and testing needed for COVID-19 or other diseases as well as biotechnology company manufacturing workers that have been designated critical healthcare infrastructure workers.***

Critical industry workers, such as those in the biopharmaceutical and sectors, should also be included in the early wave of vaccinations. We urge you to use the Department of Homeland Security (DHS) Essential Critical Infrastructure Workers definition for the “essential workers” category in ACIP’s Phase 1b. Specifically, this guidance cited “workers, including laboratory personnel, that perform critical clinical, biomedical and other research, development, and testing needed for COVID-19 or other diseases” as well as biotechnology company manufacturing workers as critical healthcare infrastructure workers. Accordingly, we believe that certain biotechnology employees, including those in research and manufacturing, as well as workers contributing to the manufacturing of personal protective equipment (PPE) and sanitizers to enable safe healthcare and vaccination during the pandemic should be recognized as part of critical risk workers included in ACIP’s Phase 1b.

1. ***Medical device industry personnel that are physically involved in manufacturing and distributing medical devices and diagnostics***

Medical device industry personnel that are physically involved in manufacturing and distributing medical devices and diagnostics should be included among the 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 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.

1. 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>. [↑](#footnote-ref-1)
2. 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>. [↑](#footnote-ref-2)
3. *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](https://webstore.ansi.org/preview-pages/NEMA/preview_ANSI%2BNEMA%2BSC%2B1-2019.pdf) [↑](#footnote-ref-3)
4. 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> [↑](#footnote-ref-4)
5. 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>. [↑](#footnote-ref-5)