ALLIANCE for CONNECTED CARE

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*Submitted electronically to emergencyclinicaltrials@ostp.eop.gov*

Ms. Grail Sipes
Assistant Director for Biomedical Regulatory Policy
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

**Re: Request for Information on Clinical Research Infrastructure and Emergency Clinical Trials**

Dear Assistant Director Sipes:

The Alliance for Connected Care ("the Alliance") welcomes the opportunity to provide comments on the White House Office of Science and Technology Policy (OSTP) request for information on clinical research infrastructure and emergency clinical trials.

The Alliance is dedicated to improving access to care through the reduction of policy, legal and regulatory barriers to the adoption of telemedicine and remote patient monitoring. Our members are leading health care and technology companies from across the spectrum, representing health systems, health payers, and technology innovators. The Alliance works in partnership with an Advisory Board of more than 40 patient and provider groups, including many types of clinician specialty and patient advocacy groups who wish to better utilize the opportunities created by telehealth.

As reflected in the comments below, utilization of telehealth proliferated throughout the pandemic and has significantly improved access to care, care coordination, patient engagement, and more. Telehealth and remote patient monitoring are important tools that can be leveraged in clinical trials to bring innovative services and treatments to those with the least access to it, however there continue to be barriers in place that impede such access. In our comments, we outline licensure restrictions that present a barrier to clinical trial recruitment and diversity and present a recommendation for OSTP's consideration.

***Effective ways to increase diversity among study participants and investigators, and to expand clinical research sites into underserved areas***

Digital technology is giving health care professionals new tools to deliver care to patients in addition to giving patients new access to care. The pandemic demonstrated that digital care can build capacity for care in rural and underserved areas, and areas experiencing provider shortages. Provider shortages are associated with delayed health care usage, reduced continuity of care,

higher health care costs, worse prognoses, less adherence to care plans, and increased travel. In addition to being a tool to address such barriers, telehealth services play an important role in supplementing and strengthening clinician networks available to patients. Telehealth can be leveraged to strengthen the delivery system by providing highly specialized services in areas where clinicians with these skills are not available to consumers.

As one goal of this emergency clinical trials initiative is to support the expansion of clinical research into underserved communities, and increase diversity among both trial participants and clinical trial investigators, the Alliance believes that continuing to modernize and decentralize clinical trials is critical for creating opportunities for more diversity and patient engagement.

Obviating the need for travel time, lost wages and childcare/eldercare through use of digital technologies will significantly increase the pool of potential participants in clinical trials across geographies. Decentralizing clinical trials is also critical with respect to advancing health equity by accounting for such logistical and other participant-related factors that could limit participation, and would also help improve recruitment, retention, and participation in clinical trials.

One barrier in using digital technology in clinical trials is the state licensing limitations that effectively prohibit clinicians working on clinical trials from recruiting patients from outside the state where the clinician is licensed, thereby creating a barrier to entry for use of decentralized trials and diminishing the impact of federal changes aimed at decentralizing clinical trials. This is especially important for rare diseases affecting fewer than 200,000 people in the United States, for which utilizing clinical trials across state lines may significantly increase the likelihood of a successful and diverse clinical trial.

To address this issue, the Administration could direct the U.S. Food and Drug Administration (FDA) to provide non-binding guidance to states on how to bolster clinical trial modernization through licensure flexibilities to help catalyze change at the state level. We recommend that the FDA set up an intergovernmental working group with state and federal regulators to develop such guidance. This group will likely identify other areas beyond licensing that may need to be addressed, such as mailing of non-approved medications.

We are hopeful that OSTP would agree it is important to promote harmonization between state and federal regulators within the United States. We see efforts to mitigate state licensing limitations as one way the Administration can act to address the barriers in decentralizing clinical trials to increase their success and participation.

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Thank you for the opportunity to provide comments on this important issue. We hope you will consider this recommendation as you examine ways to increase access to clinical trials through digital technologies and see the value of telehealth in providing greater access to clinical trial participation.

We look forward to working with you and welcome further discussion on this topic. Please reach out to Casey Osgood Landry at casey.osgood@connectwithcare.org with any questions.

Sincerely,

Executive Director
Alliance for Connected Care