



March 11, 2022

The Honorable Brad Wenstrup
Treatments Subcommittee
Healthy Future Task Force
U.S. House of Representatives
Washington, D.C. 20515

The Honorable David Joyce
Treatments Subcommittee
Healthy Future Task Force
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Bruce Westerman
Treatments Subcommittee
Healthy Future Task Force
U.S. House of Representatives
Washington, D.C. 20515

Dear Representatives Wenstrup, Joyce, and Westerman:

The Alliance for Connected Care appreciates the opportunity to provide input into the request for information from the Treatments Subcommittee of the Healthy Future Task Force regarding medical innovation to supercharge the availability and development of life-saving treatments, devices, and diagnostics, while addressing rising costs to patients. We are writing in response to the question under “Goal 4: Increase access to medical innovation” of the request for information about decentralizing clinical trials in order to expand access to innovative treatments to patients through remote monitoring.

The Alliance for Connected Care (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 also 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.

The Alliance believes 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.

State regulators have a role in breaking down additional barriers in using digital technology. Most concerning is the inability of providers to practice across state lines. Licensing limitations 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 the 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.



While this is ultimately a state issue, Congress could direct the 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, whether done through regulations or legislation, 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.

The Alliance has [previously written](#) to the Senate HELP Committee in regard to this issue in response to the discussion draft of the *PREVENT Pandemics Act*. The letter was signed by 17 organizations that work in this space. There is also wide stakeholder support for innovative approaches to address care across state lines. The Alliance, along with the ALS Association and the National Organization for Rare Disorders (NORD), convened a [stakeholder letter](#) in November 2021 that was signed by more than 230 organizations urging all 50 governors to maintain or expand licensure flexibilities enacted at the start of the pandemic for the duration of the federal public health emergency, to ensure patients can continue to access needed care via telehealth with their providers in other states.

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

Thank you for the opportunity to provide comments on this important initiative. The Alliance greatly appreciates the Treatments Subcommittee's commitment to examining legislative pathways forward to increase access to clinical trials through remote monitoring and telehealth. We hope we can be a resource to you as you move forward in this work, and look forward to working with you to develop legislation around this important effort. Please contact Casey Osgood at casey.osgood@connectwithcare.org with any questions.

Sincerely,

A handwritten signature in blue ink that reads "Krista Drobac". The signature is written in a cursive, flowing style.

Krista Drobac
Executive Director
Alliance for Connected Care