

Congress of the United States
Washington, DC 20515

January 5, 2022

To All Interested Parties:

The Modernization Subcommittee of the Republican-led Healthy Future Task Force in the U.S. House of Representatives is seeking information from stakeholders and other interested parties regarding the utilization of wearable technologies, the expansion of telemedicine, and the digital modernization efforts in the United States healthcare system. “Wearable technologies” refers to devices that “enable the continuous monitoring of human physical activities and behaviors, as well as physiological and biochemical parameters, during daily life.”¹

Overview/Purpose

- To understand all situations where wearable technologies could be useful in the U.S. healthcare system, such as in clinical trials, prevention, diagnosis, post-health intervention follow up, and others.
- To determine the effectiveness of wearable technologies in those various uses to reduce costs, improve access, and improve quality as preventive health measures and early diagnostic tools.
- To examine the benefits of telemedicine expansion, interstate licensing, and reimbursement methodologies.
- To determine whether legislation is necessary to address barriers to access, costs or quality of care.
- To determine how government actors, insurers, healthcare providers, patients, and other parties can work together to share health data in a confidential, secure, and effective way.

In light of these goals, please respond to the following questions:

Wearable Technologies

All Payers

1. In what ways have private employers and insurance providers encouraged use of wearable technology for workers and enrollees to improve health and wellness? Please describe the types of wearable devices offered, the benefits offered to enrollees, and the number of participating enrollees.
 - a. Do you collect data through the device? If so, how is this data utilized?
 - b. Have you expanded the use of wearable devices during the COVID-19 pandemic? If yes, how so?

¹ <https://decemberlabs.com/blog/wearable-technology-in-healthcare/>

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Private Employers

1. Have you offered or considered offering subsidized wearables to your employees as a means of promoting wellness? If you have aggregate data on the effect of such efforts on cost or health outcomes, would you consider sharing it with the subcommittee on a confidential basis?

Insurance Providers

1. Do you currently offer a wearable device benefit to plan enrollees on any of your coverage products? If you have aggregate data on the effect of such efforts on cost or health outcomes, would you consider sharing it with the subcommittee on a confidential basis?
2. Do you offer wearable devices as a supplemental benefit within Medicare Advantage? If you have aggregate data on the effect of such efforts on cost or health outcomes, would you consider sharing it with the subcommittee on a confidential basis?
3. How do Medicare reimbursement policies affect -up of wearables for Medicare beneficiaries and in the non-Medicare population?

Manufacturers and Developers

1. What are some opportunities for and barriers to development of new wearable technologies?
2. How can wearable technologies help improve the lives of those with chronic conditions or disabilities?
3. How do government research entities, such as NIH, AHRQ, and PCORI study wearable devices?
 - a. Is the FDA regulatory scheme sufficient to provide clarity and keep up with innovation necessary?
4. What steps have been taken to ensure patients' data gathered from wearable devices is secure?
 - a. What steps have been taken to ensure transmission of patients' data gathered from wearable devices is secure?
 - b. What challenges to ensuring the security of patients' data gathered from wearable devices security persist?
 - c. What is Congress's role in ensuring patients' data remains secure?
5. How do reimbursement policies affect utilization of wearables?
 - a. Should wearable technology be covered by Medicare as Durable Medical Equipment (DME)?
 - b. How do Medicare coverage determinations affect utilization of wearables?
 - c. How can Medicaid programs cover wearable technologies and are any states having success using them to improve health outcomes and lower costs?

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Clinical Trial Sponsors

1. Have you used wearable technologies to facilitate the collection of data as part of a clinical trial?
 - a. If so, what have been the benefits and the challenges to collecting data using wearable technology as part of a clinical trial?
 - b. Have you considered the use of wearable technology to collect data as part of a clinical trial but refrained because of regulatory barriers or uncertainty? If so, please provide details.
2. Does FDA's regulatory framework sufficiently allow for the use of data generated from wearable technologies to support findings in clinical studies?

Telemedicine Expansion

Private Employers

1. State variation in rules and regulations surrounding telehealth can create barriers to employers when offering telehealth services to their employees, which creates equity problems for multi-state plans sponsored by national employers. Please list any state laws that create onerous barriers to providing consistent telehealth benefits through multi-state employer plans.
2. Please describe the differences in telehealth coverage offered to your employees from state-to-state.
 - a. How does the difference in coverage affect patient care and outcomes?
 - b. How does the differences in coverage affect utilization?
3. If Congress were to create a national telehealth standard under the *Employee Retirement Income Security Act of 1974* to provide consistent national telehealth coverage requirements that adopt the same standard of care as in-person care, what standards should be included?
 - a. Would a National Telehealth Standard encourage employers to adopt or expand telemedicine coverage? How so?

Employers, Payers, Providers, States, and other Stakeholders

1. Which flexibilities created under the COVID-19 public health emergency should be made permanent?
2. How does telehealth affect healthcare costs in the short-term, medium-term and long-term? Would you be willing to share aggregate cost data?
3. For what services have you seen telehealth have a substitutive effect on costs and utilization? Are you willing to share data that shows these trends?
4. What overhead costs are incorporated into reimbursement for in-person visits that are not for telehealth visits? What overhead costs are incorporated into reimbursement for telehealth visits that are not for in-person visits?

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5. Employers and plans are often faced with provider shortages in certain geographic areas. Increased use of telemedicine may help alleviate these shortages, but barriers still exist that keep providers from practicing across state lines. Should Congress allow for healthcare providers who hold a valid license in good standing in at least one state to practice via telemedicine in all other states? Why or why not?
 - a. How should this legislation address any complaints, investigations, or disciplinary actions against a provider?
 - b. How should this legislation address interstate licensure compacts?
 - c. How should this legislation address multiple jurisdiction licensure?
6. How will artificial intelligence affect access, delivery, and cost of healthcare and the role it plays in modernization?

You may answer some or all of the questions above, and your response is entirely voluntary. Your response will not be made public and will only be reviewed by Members and their staff of the Healthy Futures Task Force. Responses should be limited to 10 pages, single-spaced, 12-point type with at least one-inch margins on 8 ½" x 11" paper. They may be directed to Kendyl Willox (Kendyl.Willox@mail.house.gov), a member of the legislative staff for Representative Miller-Meeks (IA-02). If you wish to participate, please send your response by 11:59 P.M. EST on March 6, 2022. Any comments received after the deadline may not be used; however, late responses will still be accepted and considered in future discussions.

We thank you for your attention and look forward to working with you as we seek to modernize the current healthcare system through wearable technology.

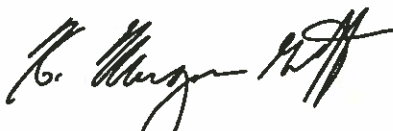
Sincerely,



Mariannette J. Miller-Meeks, M.D.
Member of Congress



Mike Kelly
Member of Congress



H. Morgan Griffith
Member of Congress