S. 4964 - Long COVID Research Moonshot Act of 2024
Section-by-Section

Title I – Long COVID Biomedical Research

Section 101 – Establishment of Long COVID Research Program

This section creates a Long COVID Research Program with the National Institutes of Health (NIH) to accelerate research on Long COVID. The program will be led by a Director, appointed by the Secretary, who will oversee and coordinate Long COVID research across NIH. The goal of the program will be to investigate the causes and effects of Long COVID, develop effective treatments and prevention strategies, and facilitate collaboration with other federal agencies and stakeholders. The Director is also tasked with ensuring that the program's activities do not duplicate existing efforts by other federal Departments or agencies.

The Director of the Long COVID Research Program is required to develop a comprehensive research plan within one year of the bill's enactment. The plan will identify current research, opportunities, and priorities for Long COVID research; evaluate progress against strategic priorities, and goals; make recommendations for coordinating research across NIH; and include goals and objectives for the Program's research activities. The Director must consult with various stakeholders and update the plan annually. The plan will be submitted to Congress, the Secretary, and posted on the NIH website.

The Director of NIH is required to establish a process to expedite the process of issuing awards for Long COVID research. The Director must make deadlines and requirements publicly available and ensure timely review of applications. In evaluating grant applications, the Director must prioritize research that tests existing interventions, focuses on pediatric patients, develops new interventions, or includes institutions serving historically underserved communities. The Director must also consider research that can begin interventions quickly, uses decentralized trials, and includes patients with similar conditions. This section also requires reasonable pricing for developed drugs and devices, considering factors like public health value, research and development costs, and global revenues.

The Director of the NIH is also required to establish a scientific review group on Long COVID and other infection-associated chronic conditions. This group will consist of leading scientific experts serving terms of up to 5 years.

This section also establishes the Long COVID Research Advisory Board to provide guidance and oversight on Long COVID research activities. The Board consists of 18 members, including scientists, healthcare professionals, patients, caregivers, and federal representatives. The Secretary appoints members, considering diversity and expertise, and engages with leading scientific experts and patient-led organizations. The Board advices on research priorities, evaluates implementation of the research plan, and provides guidance on clinical treatment research activities. The Board meets regularly, and summaries of proceedings are posted on the NIH website.

The Director of NIH is required to establish a data system for collecting, storing, and disseminating research data on Long COVID. The system will include a registry of clinical trials,

which will provide information on patient eligibility, demographic data, and trial locations. Principal investigators will be required to submit information to the registry within 30 days of announcing a clinical trial. The registry will be made publicly available in a machine-readable format. Additionally, the Director of NIH will establish a clearinghouse to provide information on research and prevention activities related to Long COVID.

This bill authorizes $1 billion in mandatory funding annually for fiscal years 2025 to 2034 for the purposes of implementing this section.

Title II – Public Health Research, Surveillance and Related Activities

Section 201 – Long COVID Programs

This section requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention (CDC), to conduct surveillance activities to understand the burden and severity of Long COVID and related conditions, with a focus on vulnerable populations like children. The Secretary will also develop and disseminate best practices for surveillance, provide technical assistance to international organizations, and conduct additional surveillance activities as needed.

Additionally, the Secretary is required to make grants to State, local, and Tribal health departments for activities related to Long COVID. Grant recipients can use funds to provide training on Long COVID identification, connect individuals to care, develop and disseminate public information and educational materials, and support laboratory capacity for screening and diagnosis, among other activities.

Lastly, the Secretary is required to collaborate with public health partners to develop a national public education campaign to educate and increase awareness about Long COVID in children and adults. The Secretary is also required to improve provider education on Long COVID by developing and making publicly availably best practices for coordinated care, clinical guidance, and provider education materials, including for pediatric populations.

The bill authorizes $101.5 million in funding annually for fiscal years 2025 to 2034 for the purposes of implementing this section.

Section 202 – Rehabilitation Research and Training Center on Long COVID Among People with Disabilities

This section amends the Rehabilitation Act of 1973 to include applied research on evidence-based treatments, services, and supports for individuals with disabilities with Long COVID or other infection-associated chronic conditions.

The bill authorizes $10 million in funding annually for fiscal years 2025 to 2034 for the purposes of implementing this section.

Section 203 – Clinical Outcomes Assessment

This section requires the Secretary, through the Commissioner of the Food and Drug Administration (FDA), to develop and validate clinical outcomes assessments to support regulatory decision-making for treatments of Long COVID, including drugs and devices. This

will establish standardized measures to evaluate the effectiveness of Long COVID treatments to ensure safe and effective treatments reach patients.

The bill authorizes $9 million in funding annually for fiscal years 2025 to 2034 for the purposes of implementing this section.

Section 204 – Electronic Reporting Form
This section requires the Secretary, through the FDA Commissioner, to develop and maintain an electronic reporting form for patients to track current and emerging treatments for Long COVID. This will enable patients to report on their treatment experiences and provide insights into treatment effectiveness.

The bill authorizes $16.6 million in funding annually for fiscal years 2025 to 2034 for the purposes of implementing this section.

Section 205 – Long COVID Care Network
This section requires the Secretary, through the Director of the Agency for Healthcare Research and Quality (AHRQ), to develop and support multidisciplinary Long COVID clinics. These clinics will provide comprehensive, coordinated care to individuals with Long COVID, with a focus on underserved populations disproportionately affected by the condition.

The bill authorizes $10 million in funding annually for fiscal years 2025 to 2034 for the purposes of implementing this section.

Section 206 – Research on Long COVID Best Practices
This section requires the Secretary, in coordination with AHRQ, to develop, test, and disseminate best practices and decision support tools for the clinical care of Long COVID and other infection-associated chronic conditions. The focus is on improving the organization, delivery, and integration of clinical and support services for Long COVID patients, ensuring high-quality care and better outcomes.

The bill authorizes $10 million in funding annually for fiscal years 2025 to 2034 for the purposes of implementing this section.