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Congressional Update: House Members Introduce Cures 2.0 Legislation

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On November 16, Representatives Diana DeGette (D-CO) and Fred Upton (R-MI) introduced the long-awaited bipartisan *21st Century Cures 2.0 Act* (Cures 2.0). Reps. DeGette and Upton have been working on Cures 2.0, a follow up to the landmark 2016 *21st Century Cures Act*, since at least December 2019, and the introduction of this bill follows the June release of a discussion draft and accompanying request for information (RFI). The legislation would authorize the creation of the Advanced Research Projects Agency for Health (ARPA-H), authorize funding for research relief through the *Research Investment to Spark the Economy* (RISE) Act, and include other provisions related to research, public health, and healthcare delivery. Given that Congress has many competing priorities in the coming months including completing the fiscal year (FY) 2022 appropriations process, it is unlikely that the legislation will become law before the end of the calendar year. Lewis-Burke will continue to monitor the legislation as it moves through Congress, including as companion legislation is developed in the Senate. More details about Cures 2.0 as introduced can be viewed below.

Research

The legislation would authorize the creation of ARPA-H, a signature Biden Administration initiative designed to drive transformational innovation in health and biomedical research. The bill would task the new agency with accelerating the discovery and application of transformational innovations in health and reducing the human and economic cost of disease. In order to achieve its goals, the bill would direct ARPA-H to:

- Promote high-risk, high-reward innovation;
- Identify and promote revolutionary advances in biomedical and health research that enable new paradigms in health;
- Accelerate transformational health advances in areas that relevant industries by themselves are not likely to undertake because of technical, financial, or other uncertainty;
- Prioritize project investments based on scientific opportunity and uniqueness of fit to ARPA-H strategies and operating practice, together with prospective impact on disease burden, both human and fiscal, including the health care fiscal liability of the federal government; and
- Partner with, and providing funding to, a broad range of institutions, including universities, national laboratories, public sector organization, private companies, nonprofit organizations, and foreign institutions.

The bill would authorize $6.5 billion over three years for ARPA-H, the same amount included in the President's FY 2022 budget request. This level is higher than what the House and Senate Appropriations Committees, who hold the power to fund the proposed new agency, have recommended for ARPA-H. The Senate would provide $2.4 billion over three years for ARPA-H in its FY 2022 spending bill, while the House would provide $3 billion over three years. Of note, Representative Anna Eshoo (D-CA) has also introduced a bill to create ARPA-H that would authorize $3 billion for ARPA-H. Beyond these differences

in topline funding level, a key point of contention across these bills and among members of Congress is whether ARPA-H should be housed within NIH or more broadly within the Department of Health and Human Services (HHS). The Biden Administration's FY 2022 budget request and Cures 2.0 would place ARPA-H within NIH, while Rep. Eshoo's legislation would house the agency within HHS and the House and Senate appropriations bills are more ambiguous on its location.

In addition to provisions related to ARPA-H, the research title of the legislation includes the *RISE Act*, which would authorize $25 billion in funding for research agencies, including $10 billion for the NIH, to provide supplemental funding to universities and independent research institutions to help offset the costs and lost research productivity due to pandemic related closures of laboratories and suspension of research projects.

The legislation also reauthorizes the Research Policy Board until 2026. Created in the *21st Century Cures Act*, the Research Policy Board requires the Office of Management and Budget (OMB) to establish an advisory committee, known as the Research Policy Board, that is charged with making recommendations on modifying or harmonizing regulations pertaining to federally funded research in order reduce administrative burden.

Public Health

The legislation would launch several new public health initiatives in preparation for future pandemics, including the development of a National Testing and Response Strategy to assess and develop best practices for testing, vaccine administration, medical supply readiness, domestic drug manufacturing, and data sharing infrastructure. Additionally, the legislation would authorize $25 million in funding for the Centers for Disease Control and Prevention (CDC) to carry out a national vaccine awareness campaign and $25 million to strengthen the nation's immunization information systems across FY 2022 to 2024. Other areas of note include the establishment of a "Learning Collaborative" to further examine implications of "long COVID" symptoms through a series of virtual meetings inclusive of researchers, providers, data scientists, and consumer advocates. Additionally, the legislation would establish NIH grants to research the long-term effects of COVID-19 in children. The legislation also includes the *Pioneering Antimicrobial Subscriptions to End Upsurging Resistance* (PASTEUR) Act, which would invest in programs to address antimicrobial resistance.

Patients and Caregivers

The legislation includes several provisions relevant to improving patient experiences, including authorizing $25 million in funding for FY 2022 through FY 2024 to provide educational programs and training for caregivers. The legislation would also require drug manufacturers to collect and report on patient experiences during clinical trials in a transparent and meaningful way, and require the U.S. Food and Drug Administration (FDA) to take this patient experience information into account when making decisions on drug approvals and authorizations. Cures 2.0 would also seek to improve diversity in clinical trials, by calling on the FDA to provide an updated report on the inclusion of demographic subgroups in trials, commissioning a U.S. Government Accountability Office (GAO) study on barriers to diverse participation in clinical trials, and directing the Secretary of HHS to organize a public awareness campaign to increase understanding of clinical trial participation in minority communities.

Centers for Medicare and Medicaid Services (CMS)

The legislation includes several provisions impacting telehealth policies. Notably, the legislation calls for increased integration of telehealth into state Medicaid programs, and would permanently remove

Medicare's geographic and origination site requirements for providers to be reimbursed for telehealth services. The legislation would also provide the Secretary of HHS with the authority to expand the types of providers that can utilize telehealth in their practices.

The legislation would direct CMS to report to Congress on payment and coverage options for digital therapies that include wearables, digital applications, and platforms. In addition, the legislation seeks to ensure reimbursement for breakthrough devices, defined as devices where no benefit category currently exists.

The legislation proposes an expansion of Medicare coverage for genomic precision medicine consultations. To qualify for reimbursement, the consultation would have to be provided by a licensed clinical pharmacist who has earned a doctoral degree in pharmacy.

The legislation includes the *Precision Medicine Answers for Kids Today Act,* which aims to increase access to diagnostic testing by establishing a demonstration project and providing federal support for the use of genetic and genomic testing for pediatric patients with rare diseases.

Food and Drug Administration (FDA)

The legislation calls for the FDA to report to Congress on how the agency is fostering greater collaboration and alignment within the agency with respect to the regulation of digital health technologies. The legislation would ask the FDA to discuss how it reviews digital endpoints and digital biomarkers, the acceptance of decentralized trials, the use of digital health technologies in patient-focused development of products, and the use and validation of digital health technology tools.

The legislation calls for the creation of a grant program within FDA for novel designs in the creation of clinical trials for drugs. In awarding funds under the program, the Secretary of HHS should prioritize the incorporation of digital health technologies and real-world evidence in the development of drugs. In addition, the legislation calls on the agency to issue guidance on the use of real-world evidence in evaluating the safety and effectiveness of drugs after they are approved. Additionally, the legislation would direct the Secretary of HHS to create a "Real World Evidence Task Force," which would be comprised of the Secretary of HHS, the Administrator of CMS, the Commissioner of the FDA, the Director of the NIH, and a private sector designee.

The legislation would direct the FDA to report to Congress on the current state of gene therapy, and the foreseeable challenges the agency expects to face over the next ten years. The legislation also includes a section requiring improved communication between FDA and CMS with regard to breakthrough therapies, fast-tracked products, or products eligible for accelerated approval.

The legislation would create two new institutes at the FDA. One institute would focus on a group of diseases that negatively affects at least one major body system, represents a major disease burden in the U.S., affects at least an estimated 50 million Americans, contributes to increasing health expenditures, for which COVID-19 exacerbates symptoms or causes serious complications, and for which products are approved by the FDA at a lower rate than products for other disease groups including those that have gone through abbreviated pathways. The second institute would focus on diseases that affect fewer than 200,000 Americans individually, affect over 30 million Americans collectively, where over 90 percent of the diseases have no FDA approved therapy, and over 50 percent of the patients are children.

The legislation would direct the FDA to issue revised guidance and provide more clarity regarding the development and submission of chemistry, manufacturing, and control information for breakthrough therapies, fast tracked products, accelerated approvals, and regenerative advanced therapies. Distinct from earlier discussion drafts of Cures 2.0, this legislation would direct the FDA Commissioner to convene a meeting with drug and medical device developers, patients, and other stakeholders to gather recommendations on approaches to encourage the adoption of decentralized clinical trials.

The legislation would amend the *Food, Drug, and Cosmetic Act* by calling for the inclusion of clinical evidence, patient registries, or other sources of real-world evidence in post-approval studies for accelerated approvals.

Sources and Additional Information:

- The Cures 2.0 legislation is available at https://degette.house.gov/sites/degette.house.gov/files/Cures%202.0_DISCUSSION%20DRAFT.pdf.
- A section-by-section summary of the legislation is available at https://degette.house.gov/sites/degette.house.gov/files/Cures%202.0%20Section%20by%20Section%20Summary.pdf
- Lewis-Burke's analysis of the June 2021 *Cures 2.0* discussion draft is available at https://old.lewis-burke.com/sites/default/files/congressional_update_-_house_members_unveil_cures_2.0_discussion_draft_0.pdf
- Representative Eshoo's *ARPA-H Act* is available at https://eshoo.house.gov/sites/eshoo.house.gov/files/ESHOO_042.pdf