CURES 2.0 Creates New Research Agency, Expands Telehealth

OVERVIEW

More than four years after the *21st Century Cures Act* was signed into law, Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) on Tuesday circulated a discussion draft of their proposed *Cures 2.0* legislation, setting the stage for negotiations on the long-awaited legislative package.

In addition to proposing new programs and enhancements for the CMS, the 127-page draft bill includes the *Telehealth Modernization Act*, a bill that would permanently remove Medicare's geographic and originating site restrictions and allow the Secretary to permanently expand the types of health care providers that can offer telehealth serves and the types of services that can be reimbursed under Medicare. The proposal would also create the $6.5 billion Advanced Research Projects Agency for Health (ARPA-H) the Biden administration called for in its 2022 budget proposal.

NOTABLE PROVISIONS

Centers for Medicare & Medicaid Services

Extending Medicare Telehealth Flexibilities: This policy would permanently remove Medicare's geographic and originating site restrictions which require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services. It would also allow the Secretary of HHS to permanently expand the types of health care providers that can offer telehealth services and the types of services that can be reimbursed under Medicare.

Strategies to Increase Access to Telehealth under Medicaid and Children's Health Insurance Program: This policy would provide guidance and strategies to states on effectively integrating telehealth into their Medicaid program and Children's Health Insurance Program (CHIP), review the impact of telehealth on patient health and encourage better collaboration.

Breakthrough Products Act: This policy would codify the current Medicare Coverage of Innovative Technology pathway at CMS.

Expanding Access to Genetic Testing: This policy would provide federal support for the use of genetic and genomic testing for pediatric patients with rare diseases.

Medicare Coverage for Precision Medicine Consultations: Requires the Secretary of HHS to create a pilot grant program within the Center for Medicaid and Medicare Innovation to test approaches to delivering personalized-medicine consultations

Public Health

Long-COVID: Directs HHS to conduct a large national survey of patients who self-identify as having long-COVID to assess sources of health coverage, long-term care coverage, and disability coverage. Additionally, the draft legislation directs HHS to convene a series of national meetings (virtually) to serve as the basis of an ongoing long-COVID learning collaborative with individuals and organizations representing key sectors of the health care community.

National Testing and Response Strategy: Requires a national strategy, based off lessons learned, and best practices developed, as a result of the COVID-19 pandemic, that addresses testing, data sharing infrastructure, administration of vaccines and therapeutics, and medical supply readiness to mitigate future pandemics and public health emergencies.

Pandemic Preparedness Rare Disease Support Program: Requires the Secretary of HHS to develop a plan to help rare disease patients overcome challenges in public health emergencies; and establishes a federal grant program for organizations implement the plan.

Developing Antimicrobial Innovations: This policy would establish a subscription model to pay for critically-needed novel antimicrobial drugs. HHS would provide companies with a federal payment, that is delinked from the sales or use of those newly-developed antibiotics, to ensure a predictable return on investment and improve appropriate use of the drug.

Patients and Caregivers

Ensuring Coverage for Clinical Trials Under Existing Standard of Care: Allows Medicare to cover the costs of their beneficiaries in PCORI-funded clinical trials.

Patient Experience Data: Requires drug manufacturers/sponsors to collect and report on patient experience data as part of the clinical trial. It also requires FDA to fully consider all patient experience data collected during the clinical trial; and requires reporting of patient experience data in a transparent manner that is uniform, meaningful and informative to patients and providers.

Educational Programs and Training for Caregivers: Funds educational programs and training for caregivers to learn skills which would allow them to augment a care team and complement, not compete with, a clinical visit.

Research

Research Investment to Spark the Economy: Provides $25 billion to independent research institutions, public laboratories and universities throughout the country to continue their work on thousands of federally-backed projects.

Advanced Research Projects Agency for Health: Authorizes the creation of ARPA-H. The mission of ARPA-H is to speed transformational innovation in health research and speed application and implementation of health breakthroughs by funding projects that could:

- Tackle bold challenges requiring large scale, sustained coordination; o Create new capabilities (e.g., technologies, data resources, disease models);
- Support high-risk exploration that could establish entirely new paradigms; and/or
- Overcome market failures through critical solutions, including financial incentives.
- Complement NIH's existing research portfolio and mission and the private sector's research initiatives.

ADDITIONAL INFORMATION

- Discussion Draft
- Summary
- Statement