



November 28, 2017

The Honorable Michael C. Burgess, M.D.
Chairman
U.S. House Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member
U.S. House Energy and Commerce
Subcommittee on Health
2322A Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green:

The Healthcare Leadership Council appreciates the opportunity to submit this letter regarding the Energy and Commerce Subcommittee on Health hearing on “Implementing the 21st Century Cures Act: An Update from FDA and NIH.”

The Healthcare Leadership Council (HLC) is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation’s healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible for all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC appreciates the committee’s bipartisan efforts toward the passage of the “21st Century Cures Act.” This law contains important provisions that will advance the rate of cures and treatments for millions of Americans.

Research:

HLC has been a strong proponent of important initiatives that were included in the 21st Century Cures Act. Specifically, HLC supports the Innovation Fund, which advances important initiatives at the National Institutes of Health (NIH), including the Precision Medicine Initiative, the Cancer Moonshot Initiative, the BRAIN Initiative, and the Regenerative Medicines Initiative. We encourage the administration to continue

working with the private sector on these and other crucial research efforts by reducing barriers to broader data sharing among private sector and government entities.

Specifically, we encourage the administration to allow private sector organizations greater access to research identifiable files for regular, systematic use that proactively evaluates the safety and effectiveness of medical products and services. Currently, these files are only made available to researchers on a per-study basis. We also encourage the administration to streamline the process by which the Centers for Medicare and Medicaid Services (CMS) approves researchers, as the current process is extremely long and administratively burdensome. Finally, we urge the Department of Health and Human Services (HHS) to harmonize CMS data use agreement protections (as required by the Privacy Act of 1974 and Privacy Act regulations in 45 CFR Part 5b) with the data use agreement provisions in the HIPAA privacy rule. Data use agreements should follow a standardized format across all federal government agencies.

Medical Devices and Drugs:

HLC supports many of the medical device and drug provisions included in the 21st Century Cures Act. We look forward to the Food and Drug Administration's (FDA's) implementation of these provisions, which aim to reduce the regulatory burden associated with medical device and pharmaceutical product regulation. We particularly appreciate an expedited review process for breakthrough devices as well as simplifying the process for exempting certain devices from the premarket notification requirement. We also look forward to working with the FDA as it establishes its program to evaluate the potential use of "real world evidence" in support of applications for new indications for FDA-approved drugs.

Health information technology:

HLC has a long history of promoting health information systems' interoperability across organizations and applauds Congress for including important provisions in the 21st Century Cures Act that advance nationwide interoperability. HLC members look forward to working with HHS as the agency develops regulations related to practices by health information technology vendors and healthcare providers who intentionally block or otherwise inhibit health information exchange. In 2014, the CEOs of HLC declared their opposition to technology products and practices that block or otherwise inhibit health information exchange. HLC supports efforts by policymakers to address products and practices that intentionally block the sharing of information, or that create structural, technical, or financial impediments or disincentives to the sharing of information.

Mental health and substance use disorders:

Finally, HLC appreciates the shift in thinking in the 21st Century Cures Act that promotes advances in treating mental health and substance use disorders. Enhanced cooperation among agencies and providing funding for the development of innovative evidence-based models of treatments to address mental health and substance use disorders is an important step forward provided by the Act.

To build on these important advances, HLC encourages the committee to promote greater data sharing to coordinate the care of patients dealing with mental health or substance use disorders. Specifically, we urge the committee to pass H.R. 3545, the Overdose Prevention and Patient Safety (OPPS) Act, which would enable providers to better treat those suffering from substance use and alcohol disorders by aligning their substance use information with their medical information under the HIPAA privacy rule. This holistic approach to effectively treating patients suffering from addictive disorders is long overdue.

We applaud the committee's leadership to ensure swift and appropriate implementation of the 21st Century Cures Act and look forward to working with the committee and the administration on this effort. If you have any questions, please do not hesitate to contact Tina Grande, Senior Vice President for Policy at HLC, at (202) 449-3433 or tgrande@hlc.org.

Sincerely,

A handwritten signature in cursive script that reads "Mary R. Grealy".

Mary R. Grealy
President