



STATEMENT FOR THE RECORD

House Energy and Commerce Committee
Subcommittee on Health: *Markup of the 21st Century Cures Act*

May 14, 2015

Dear Chairman Upton, Representative DeGette, Ranking Member Pallone, Chairman Pitts, and Representative Green:

The Healthcare Leadership Council (HLC), a coalition of chief executives of the nation's leading healthcare companies and organizations, appreciates your efforts and the bipartisan work toward the release of the latest draft of the "21st Century Cures Act" by the House Energy and Commerce Committee.

HLC strongly supports the effort to modernize the discovery, development and delivery of innovative treatments and cures to patients nationwide and is pleased to see this effort led on a bipartisan basis by Energy and Commerce Committee Chairman Fred Upton (R-MI), Oversight and Investigations Subcommittee Ranking Member Diana DeGette (D-CO), full committee Ranking Member Frank Pallone, Jr. (D-NJ), Health Subcommittee Chairman Joe Pitts (R-PA), and Health Subcommittee Ranking Member Gene Green (D-TX). HLC and its broad membership have actively worked to support many sections of this draft legislation.

HLC supports inclusion of provisions designed to speed the clinical trial process and reduce unnecessary administrative burdens. In particular, we applaud members of the Committee for addressing the following topics:

- Electronic health record interoperability: HLC members, who are leaders in every healthcare field, have agreed on the need for an interoperable health IT infrastructure constructed in a way that is both beneficial to consumers and realistic and sustainable for industry. We are pleased that the discussion draft recognizes the very real problem of information blocking as emphasized to Congress by HLC and its members and includes an enforcement mechanism for electronic health record products that knowingly block information. We look forward to working with Congress and the administration to ensure that a clear

set of interoperability outcome measures leave room for innovative private sector efforts to interoperate.

- Modernization of research restrictions related to the Health Insurance Portability and Accountability Act (HIPAA): We believe that existing medical privacy laws are serving the public well. Nevertheless, the HIPAA updates in this legislation are beneficial to enabling optimal use of today's health databases for research. HLC's previous testimony before this committee encouraged members to keep in mind that HIPAA was created at a time in which policymakers weren't thinking about the knowledge that could be gained by accessing data residing in large databases and the technological ability to process that data very rapidly. We appreciate Congressional efforts to incorporate our previously shared concerns and support the committee's effort to ensure that data can be used effectively for research.
- Sensible Oversight for Technology Which Advances Regulatory Efficiency (SOFTWARE) language: HLC members recognize the benefit of enhanced regulatory clarity regarding mobile medical applications, clinical decision support tools, electronic health records, and other software. We appreciate the bipartisan and multi-stakeholder approach taken by the committee to provide greater clarity around software regulation. Providing more certainty related to software regulation will encourage continued innovation in this field.
- Telehealth as a tool for improving healthcare delivery: Throughout the 21st Century Cures Initiative, HLC has emphasized the importance of including telehealth provisions in the legislation. Substantial changes to current telehealth policy are needed to equip healthcare providers with tools to ensure they can meet the demands of an innovative healthcare system, dramatically changing patient demographics, and an increased chronic disease burden. HLC's multisector, consensus principles on workforce identify telehealth as a top priority, and stress the importance of significantly addressing the current restrictive reimbursement, licensure, and other regulatory barriers. We are pleased members of Congress recognize the importance of telehealth as part of innovative care delivery by including language in the 21st Century Cures package. We look forward to continuing to collaborate with members of the bipartisan congressional telehealth working group as they develop telehealth policy that will increase value and improve patient outcomes.

HLC encourages the Committee to reinsert language that would expand access to Medicare and Medicaid claims data held by Centers for Medicare and Medicaid

Services (CMS): While the provisions on expanding the sharing of data generated through NIH-funded research are important, HLC strongly believes that any effort to accelerate treatments and cures must include robust real-world data sharing from CMS, as well. As publicly-funded entities, federal agencies have an obligation to share data that will accelerate efforts to develop new treatments and cures in the private sector. As HLC testified before the House Energy and Commerce health subcommittee last summer, any standard that restricts access to critical federally-held data is detrimental to our shared goals for medical and human progress. **We strongly believe that legislative language encouraging greater data sharing with the private sector by federal agencies should be included in this 21st Century Cures effort.**

Once again, on behalf of the Healthcare Leadership Council, I applaud you for your bipartisan work to support innovative treatments and cures for patients. We stand ready to assist and support your efforts.

Sincerely,



Mary R. Grealy
President

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2015

(Alphabetized by Company)



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