



March 1, 2019

Chairman Lamar Alexander
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC 20510-6300

RE: Request for Information on Cost and Burden Reduction in Healthcare

Dear Chairman Alexander:

Thank you for the opportunity to provide our thoughts on ways Congress might lower health care costs. We agree that little can be done to control the cost of health coverage without fully examining and understanding the factors that drive medical expenses.

The Health Innovation Alliance (HIA), formerly Health IT Now, is comprised of patient organizations, provider groups, payers, employers and technology companies who came together to advocate for the use of technology and data to improve healthcare. We support improved connectivity, modern privacy laws and regulations, and fundamentally redefined care delivery to improve access and value. Our goal is to produce an efficient and effective healthcare system where innovative solutions - focused on patients, and designed by doctors and the marketplace - are rapidly adopted and put to use.

Congress passed the HITECH law 10 years ago. While incentives in the law lead to widespread adoption of health IT, we largely digitized existing processes, rather than disrupt and transform the costly and too often ineffective health system. As a result, costs are greater due to a number of known problems, including duplicate tests, medication errors, and failures in coordinating care. These problems lead to billion in needless costs every year.

Below we outline reforms Congress might take to address these issues. These recommendations reflect the viewpoint of HIA and should not be attributed to any of our individual member organizations. We encourage you to act this year to lower health care costs.

Advance Healthcare Connectivity. Connectivity means more than sending or receiving information - it is a process that ensures data is available on demand, it can be used, and that it is useful. While nearly all U.S. hospitals have implemented an EHR system, only 41 percent can send, receive, find, and integrate information the way consumers expect of other industries. Further, 47 percent of hospitals experience greater challenges exchanging EHRs across different vendor platforms. HHS estimates that we could reduce Medicare spending by \$3.12 billion annually if health information exchanges were interoperable. In addition, doctors and other providers spend nearly 40 percent of their time on data entry instead of caring for patients. Interoperability will allow doctors to spend more time face to face with patients and save time in delivering that care, which in turn will save \$3.3 billion annually.

To improve health care connectivity, Congress should:

1. Encourage HHS to finalize information blocking rules consistent with Congressional intent this year;
2. Accelerate the speedy implementation of application programming interfaces (APIs) in federal healthcare programs to ensure timely access to electronic health information by patients and practitioners alike;
3. Align incentives in federal programs to reward practitioners for accessing existing EHI instead of ordering medically unnecessary services, or duplicative tests;
4. Establish a carve out to the Stark and Anti-Kickback laws to allow for a nominal, fair market value payment for the transfer of information to help finance interface infrastructure. Currently, referring clinicians are required to take on the full cost of building and maintaining interfaces to send data electronically because receiving providers are legally prohibited from paying for the transfer of that data – despite the fact that the receiving clinicians experience the full benefit of the electronic transfer.
5. Allow the development of a national unique personal identifier (NUPI) or national identity management system (NIMS) to reduce administrative costs and improve the efficiency of identifying relevant patient information in federally funded healthcare programs;
6. Direct HHS to extend its Blue Button 2.0 initiative, which provides CMS claims data access to patients, to include the patients’ clinicians and their technology partners;
7. Update ClinicalTrials.gov to align with the technical standards established in the Promoting Interoperability (PI) program as well as those used by the Veterans Administration (VA); and
8. Support next-generation connectivity infrastructure, such as 5G, to address unmet, technology-enabled healthcare needs in rural settings and with disadvantaged geographies and populations.

Modernize HIPAA. The HIPAA privacy framework is outdated and should be modernized. Since the original passage of HIPAA in 2001, society and culture has become much more comfortable sharing and using information, including health information, for a variety of purposes, so long as that purpose is known and the information is secure. HIPAA should be modernized to reflect these advances in tandem with any consumer data privacy initiatives to allow meaningful data portability both in and out of the healthcare setting. While privacy has been a politically charged issue, it would be truly unfortunate if lawmakers engaged in an exercise to expand protections for consumer privacy for social media purposes and did not take the opportunity to bring healthcare privacy into the modern era.

Specifically, we recommend Congress take the following steps:

1. Create a national, legal framework for consumer-directed privacy and security for health information and that exists within an overarching architecture for all consumer and commercial data;
2. Facilitate individual access and rights to grant access to private health information in the same way patients may direct other consumer data;
3. Test the use of blockchain to better secure personally identifiable health information; and
4. Establish a national, electronic and privately administered system to account for patient authorization for use of information that could be required whenever an authorization needs to be checked for treatment or research issues.

Streamline Federal Regulation. There are many overlapping or conflicting laws that govern healthcare technology. Regulation and approval processes slow down the adoption and use of digital health and innovative healthcare technologies. An agile regulatory framework that quickly approves, covers, reimburses and enhances innovative products is needed to ensure the best outcomes for patients, taxpayers, and healthcare providers. Speed to market should be a guiding principle.

We urge Congress to:

1. Allow for FDA to leverage third-party accreditation and certification schemes for information technologies, platforms, or infrastructure with healthcare applications;
2. Create a de novo certification pathway for new information-driven technologies, platforms, and infrastructure with healthcare applications;
3. Expand patient safety organization-style legal protections to users and developers of the algorithms used for artificial intelligence so that uptake is expanded, and we can learn from any errors or safety events;
4. Expand the availability and permissible uses of data collected pursuant to federally funded programs, including Medicare, Medicaid, CHIP, Tricare, the Veterans Administration (VA), the Federal Employee Health Benefits Program, and the Indian Health Service. The current Qualified Entity program currently permits the release of only Medicare Part A, B and D data, and Medicaid and CHIP data, but not TRICARE, FEHB and VA data. Congress should expand available data to include claims and quality data from these programs and provide it to commercial, state governmental, research organizations, nonprofit and public entities for the express purpose of managing costs and analyzing the impact of payment and other policies on costs and market competition. Current rules permit the sharing of public data for the express purpose of improving quality, but not efficiency. This makes little sense. Such data should be available to power tools like AI, population and individual analytics.
5. Pass legislation to clarify regulatory authority with regards to emerging technologies such as artificial intelligence (AI).

Eradicate Preventable Mortality in Hospitals. Every year, more than 500,000 Americans die in hospitals from preventable causes, making it the third leading cause of death. While the healthcare community continues to work tirelessly to avoid these tragedies, there are still significant gaps in our understanding of what is working –as well as what isn’t– in patient safety. The HELP Committee held a number of hearings on these issues in the 114th and 115th Congresses, but few legislative initiatives made it past their introduction.

Specifically, the committee should:

1. Direct HHS to publish a list of HACs that are the leading causes of preventable mortality;
2. Expand information blocking rules to include medical devices;
3. Eliminate the “gag rule” that prohibits HHS from releasing results of hospital accreditation surveys for participation in the Medicare program; and
4. Require hospitals to increase operational transparency and make public, quarterly, electronic, de-identified reports on the incidence rates of hospital acquired conditions.

Leverage Technology to Fight the Opioid Crisis. The use of technology is a critical component to combat the opioid crisis, from prevention all the way through to treatment. It should be fully leveraged in areas such as addressing gaps in current prescription drug monitoring programs (PDMPs), thwarting fraudulent opioid transactions before medication leaves the pharmacy counter, removing barriers to treatment via telehealth and encouraging innovative uses through advanced and predictive analytics.

Specifically, the committee should:

1. Pass legislation in support of a Prescription Safety Alert System (RxSAS) utilizing existing industry-proven electronic healthcare communication standards to improve the information presented to clinicians at the points of prescribing and dispensing. The concept is further explained in the attached white paper authored by the National Council for Prescription Drug Programs, titled *NCPDP Standards-based Facilitator Model for PDMP*; and

2. Pass legislation to reform the outdated 42 CFR Part 2 regulation to align substance use disorder treat records with HIPAA for the purposes of treatment, payment, and healthcare operations to ensure coordinated care and patient safety.

Conclusion

The Health Innovation Alliance is encouraged that the committee is soliciting solutions through an inclusionary and transparent process. We encourage you to pass these reforms this year to improve outcomes and to lower costs so that health care works better for all Americans.

Sincerely,



Joel C. White
Executive Director