



Key 2016 Accomplishments

The Confidentiality Coalition, convened by the Healthcare Leadership Council (HLC), is a broad group of organizations working to ensure that policymakers balance appropriately the protection of confidential health information with the efficient and interoperable systems needed to provide high quality care. We advocate for policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, supporting policies that enable the essential flow of patient information that is critical to the timely and effective delivery of healthcare. Timely and accurate patient information leads to both improvements in quality and safety and the development of new lifesaving and life-enhancing medical interventions.

Ensuring Confidentiality and Security

Data breaches and cyberattacks continue to plague the healthcare industry and, given the value of this information on the black market, will continue to do so for the foreseeable future. Significant steps are underway to improve security, including the implementation of the national cybersecurity threat information-sharing legislation passed in December 2015, its corresponding healthcare task force, and updates by both public and private sector entities working to help healthcare organizations face these threats. In 2016, the Coalition brought a unified healthcare voice to influence Congress and the federal government on cybersecurity and data breach activity.

- ✓ Supported the work of the Health Care Industry Cybersecurity Task Force pursuant to our involvement in its creation through work with Congress on the Cybersecurity Information Sharing Act (CISA).
 - The coalition submitted comments to the task force addressing top cybersecurity risks and concerns, best practices, gaps and challenges for health information sharing, and efforts needed to better prepare the healthcare industry.
 - The coalition monitors federal cybersecurity activities and emphasizes the importance of avoiding duplicate or conflicting privacy and security rules with efforts already underway in the health sector.
 - In the spring, the Coalition successfully assisted several Coalition members with nominations to the task force.
- ✓ Met with an expert from the Department of Health and Human Services (HHS) Office for Civil Rights (OCR), who spoke about the agency's recent ransomware guidance, as well as OCR's regulatory approach to ransomware attacks. The guidance, published last summer, describes ransomware attack prevention and

recovery from a healthcare sector perspective, including the role of HIPAA-covered entities and business associates in preventing and recovering from ransomware attacks, and how HIPAA breach notification processes should be managed in response to a ransomware attack.

- ✓ Serves as an important voice on potential data breach legislation in both the House and Senate. The Coalition communicates the potential problems with dual regulation of HIPAA-covered entities and their business associates by non-HHS agencies. As a result of these meetings, draft data breach notification bills have been edited to be more favorable to healthcare organizations.

Simplifying Health Information Flow and Patient Access

The HHS OCR continues to regulate the protection of individuals' medical information, as well as their right to gain access to that information under the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules. Recently, HHS has increased efforts to promote the sharing of information, in order to support broader interoperability and consumer uses, such as patient-powered research networks. In 2016, the Coalition served as a partner and resource for Congress and the Administration as we work to unlock new information that will accelerate medical innovation while continuing to protect health information.

- ✓ Co-led an advocacy campaign on patient “matching” which resulted in language enabling HHS to provide technical assistance to private-sector initiatives promoting patient safety by correctly matching them with their health information. Nearly two dozen healthcare organizations joined, including key trade associations.
- ✓ Submitted a statement for the record in connection with the House Energy and Commerce Subcommittee on Communications and Technology hearing on “Modernizing the Telephone Consumer Protection Act (TCPA).” The letter recommended that Congress amend TCPA to allow greater flexibility and regulatory clarity for healthcare organizations to communicate with patients.
- ✓ Continued to work with a coalition of healthcare stakeholders committed to aligning federal confidentiality regulations for substance abuse (42 CFR Part 2) with HIPAA to allow appropriate access to patient information that is essential for providing comprehensive care. The group advocates with Congress to allow appropriate access to a patient’s entire medical record, including addiction records, to ensure that providers and organizations have all the information necessary for safe, effective, high-quality treatment and care coordination that addresses all of a patient’s health needs.
 - Commented on the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Notice of Proposed Rulemaking (NPRM) on the “Confidentiality of Substance Use Disorder Patient Records.” The comments commended SAMHSA for its effort to create an additional patient consent pathway for providers involved in a patient’s care, but expressed concerns that the proposal may remain too restrictive and may

still lead to barriers in the integration of substance use disorder treatment records into coordinated care models.

- ✓ Worked closely with the Senate Health, Education, Labor, and Pensions (HELP) Committee and House Energy and Commerce Subcommittee on Health staff on revising bipartisan draft legislation to improve health information technology and medical innovation.
 - Worked closely with Congressional staff, assisting efforts to enact reforms through the 21st Century Cures initiative to reduce the regulatory burden of HIPAA and to accelerate the use of digital health data and tools in developing treatments and cures.
 - Drafted several rounds of feedback and remained active as the “21st Century Cures Act,” proposals moved through the House and Senate.
- ✓ Participated in a National Governors Association (NGA) effort to improve health information flow across state lines. The Coalition advocated for consensus among states to mitigate the challenge of many conflicting and burdensome state privacy laws that undermine the delivery of healthcare. Continue to engage as NGA works on its “interoperability roadmap.”
- ✓ Testified before the House Oversight and Government Reform Committee on “Opportunities and Challenges in Advancing Health Information Technology.” Highlighted were some of the recommendations on challenges with conflicting state privacy laws and the need for greater federal leadership on patient-identifier efforts.
- ✓ Contributed to HLC-launched report, *Viable Solutions: Six Steps to Transform Healthcare Now*. Several of the report recommendations focused on challenges related to health information privacy. Specifically, the report supported patient matching/patient identifiers, harmonizing legal privacy requirements for research, greater government data sharing, and efforts to harmonize conflicting state privacy laws.
- ✓ Commented on the NPRM on “Federal Policy for the Protection of Human Subjects.” The coalition commended HHS proposals designed to streamline and improve the institutional review board (IRB) process, while expressing concerns that certain consent proposals would impede or delay research studies.
- ✓ Continues to lead the health industry in seeking an alternative to the unworkable “accounting-of-disclosures” proposed HIPAA privacy regulation. According to various sources, the HHS Office for Civil Rights (OCR) will revisit the issue.

Convening and Educating Leaders

The Confidentiality Coalition is the only organization bringing together hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and

research organizations, clinical laboratories, patient groups, and others on these important issues. Through our unique diversity, we are able to provide consensus perspectives on the impact of legislation or regulation affecting the privacy and care of health consumers

- ✓ Convened members to meet with the FTC to discuss the agency’s ongoing activity in the healthcare arena. The FTC has been particularly active in monitoring wearable devices and other non-HIPAA health data sources. HLC and the Confidentiality Coalition continue to monitor increasing FTC involvement in healthcare, particularly around data breaches and regulation of non-HIPAA data.
- ✓ Convened members to meet with Office of the National Coordinator for HIT Chief Privacy Officer, Lucia Savage, to discuss the agency’s recent privacy-related work. Of particular note was the July report, “Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA.” This report is intended to be a clear and detailed analysis of the regulatory structure for health data not covered by HIPAA. The report does not provide recommendations for legislative or regulatory action, but does identify perceived gaps in the regulation of health information privacy and security.
- ✓ Regularly featured at key health privacy briefings and conferences, such as the “National HIPAA Summit” and the “Privacy and Security Forum.”
 - In July, the Confidentiality Coalition held its annual “HIPAA 101” congressional briefing, joined by experts from Medtronic and IMS Health. Speakers discussed the HIPAA privacy rule, security rule, cybersecurity, and important issues, such as data breaches, ransomware, and the sharing of information across state lines. The event had record congressional staff turnout
 - In May, HLC President Mary R. Grealy moderated a panel of ONC executive staff at the annual Health Datapalooza conference. ONC efforts to address a number of HLC and consumer priorities related to privacy and the use of HIT were discussed.
- ✓ Convened members to meet with leaders from the HHS OCR for a discussion of the agency’s activity in health privacy. In addition to HIPAA enforcement, patient access, and the ongoing audit program, OCR also spoke with the coalition about its work on the White House Precision Medicine Initiative Privacy and Trust Framework and ongoing work on the security framework for the initiative.
- ✓ The Confidentiality Coalition continues to provide a positive public voice for ensuring the right balance between the protection of confidential health information and the efficient and interoperable systems needed to provide high quality healthcare. These efforts are communicated through comment letters, correspondence, meetings, press activities, and the Coalition’s website, <http://www.confidentialitycoalition.org>.