August 1, 2024

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, M.D.
2313 Rayburn House Office Building
Washington, DC 20515

RE: Request for Information on Realizing the Goals of the 21st Century Cures Act

Submitted Electronically to cures.rfi@mail.house.gov

Dear Congresswoman DeGette and Dr. Bucshon:

Thank you for the opportunity to respond to the request for information on furthering the goals of the 21st Century Cures initiative. We appreciate your leadership in fostering health care innovation through your efforts to develop and support the original Cures Act, Cures 2.0, and now this initiative.

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs. One of the cornerstones of HIA is interoperability, something that can only be achieved when data is being shared appropriately between actors in the healthcare system.

The 21st Century Cures Act made great leaps forward in supporting the sharing of health information to improve care, outcomes, and costs. Our coalition was heavily involved in crafting and implementing those policies, and we look forward to working with you to push health information, technology, and data issues further. HIA convened a work group in 2021 and 2022 to determine policies still needed to advance the access, exchange, and use of health information. We released a report outlining recommendations in six key areas to help achieve these goals:

- Enabling data to work for patients and providers at the point of care,
- Leveraging state of the art medical devices to improve patient care,
- Establishing clear protections from HIPAA penalties for patient information requests,
- Informing medical research and innovation with better information,
- Standardizing, collecting, and using social determinants of health data, and
- Improving public health data collection and reporting.

We still believe that all of these recommendations are relevant and needed, and we have attached the full report to this letter. We look forward to working with you to turn our recommendations into legislation and law.
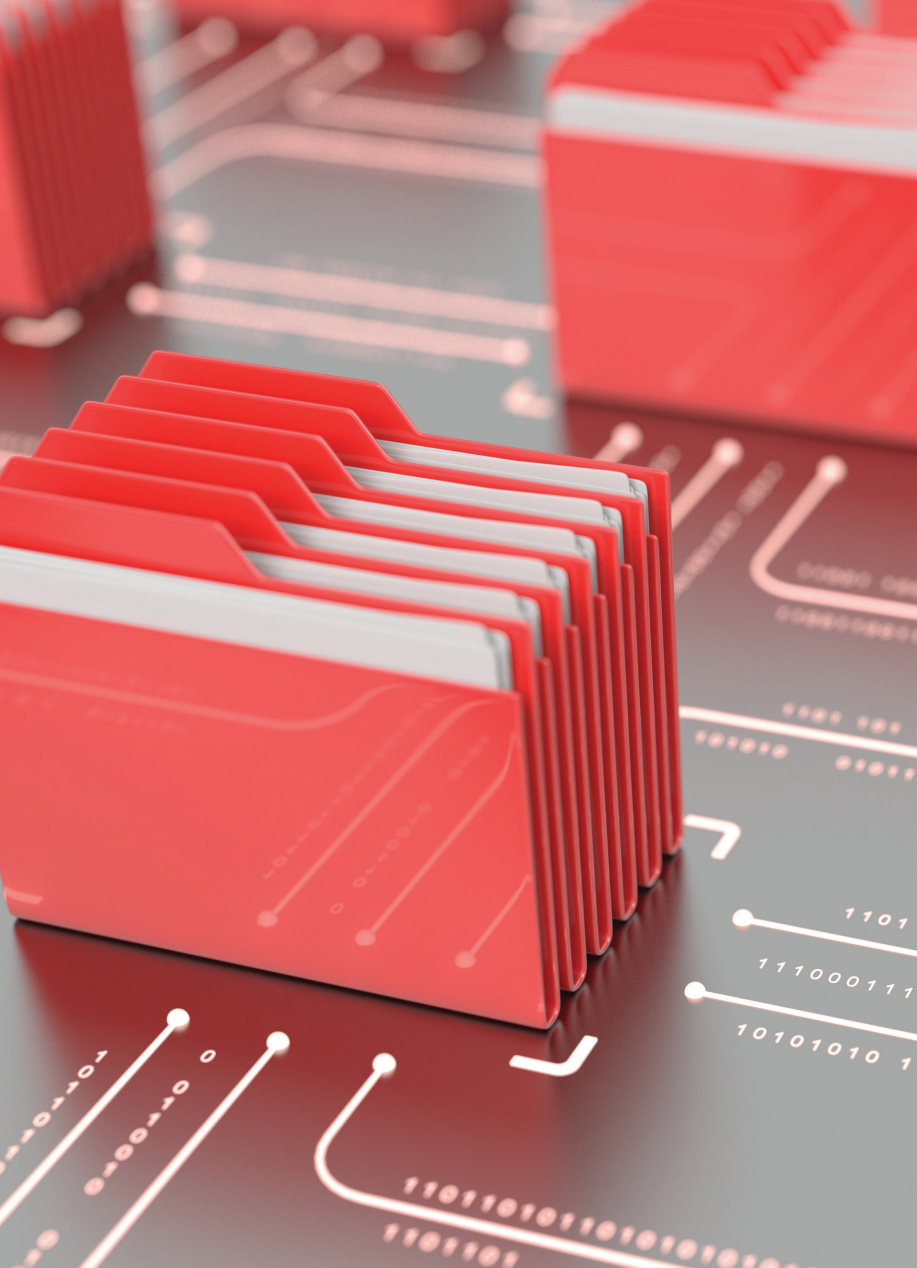
We again thank you for the opportunity to provide our feedback on this important topic, and we look forward to partnering with you and your teams in the goal of continuing to promote interoperability.

Sincerely,

Brett Meeks
Executive Director

Attachment

HEALTH **INNOVATION** ALLIANCE

Interoperability Workgroup
Report

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ABOUT THE
HEALTH INNOVATION ALLIANCE

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs. Formed in 2007, HIA has been on the front lines of federal policy related to health care technology and interoperability since our inception. HIA staff and members have helped pass the original Health Information Portability and Accountability Act (HIPAA), helped influence the Health Information Technology for Economic and Clinical Health (HITECH) Act, and helped draft, negotiate, and pass the 21st Century Cures Act.

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Foreword

The 21st Century Cures Act made significant changes to the treatment of health care data, but more than five years have passed since it became law, and many of the provisions have yet to be implemented. While there have been tremendous gains to improve access, exchange, and use of health information, an unclear regulatory environment is stifling private sector advances to interoperability. The pandemic has highlighted major issues with sharing health care information, particularly with respect to public health. According to the Office of the National Coordinator for Health Information Technology (ONC), 70 percent of doctors still rely on fax machines to exchange health information.[1] We experienced this firsthand during the pandemic when too many phoned and faxed in COVID-19 information that made it unreliable, untimely, and prone to error.

Today, there is tremendous interest and potential among hospitals, doctors, payers, and others to share patient information to improve outcomes and coordinate care for patients. Expansion of the patient right of access and the connection of that right to the availability of open application programming interfaces (APIs) hold tremendous promise for patients to take charge of their own health information. Additionally, more and more health care apps and tools are being developed and used by clinicians and patients.

For all our progress, we have a long way to go. Two years after publication of final rules detailing the interoperability and information blocking requirements of Cures, many provisions have yet to be implemented. Some requirements, including details on how information blocking will be enforced against providers, still do not have proposed regulations despite carrying an "applicability date" of April 5, 2021. Other requirements on health plans to stand up APIs carry unclear enforcement or fall under enforcement discretion until further, technical rulemaking is released.[2] ONC recently released aspirational statements on how interoperability will improve health care by 2030,[3] but for that to happen we must act now.

HIA formed the Interoperability Workgroup (IWG or workgroup), a diverse group of health care industry stake-holders, to develop policies and identify private sector actions that will improve care, outcomes, cost, efficiency, access, and population health by ONC's target of 2030. Six areas of focus were identified:

- Data That Works for Patients and Providers at the Point of Care
- Leverage State of the Art Medical Devices to Improve Patient Care
- Clear Protections from HIPAA Penalties for Patient Information Requests
- Inform Medical Research and Innovation with Better Information
- Social Determinants of Health, and
- Improve Public Health Data Collection and Reporting

HIA makes the following recommendations as a basis for achieving better interoperability and a more robust market for data sharing.

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[1] https://news.bloomberglaw.com/health-law-and-business/health-care-clings-to-faxes-as-u-s-pushes-electronic-records
[2] *See* FAQ 10 and 37 at: https://www.cms.gov/about-cms/obrhi/faqs
[3] https://www.healthit.gov/topic/interoperability/health-interoperability-outcomes-2030

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Privacy

HIA believes interoperability requires robust, clear, and trusted rules regarding the privacy and security of health information. We formed a Health Data Privacy Working Group in 2019 to begin working on improving health information privacy in the age of pervasive data and APIs. In March 2020, we outlined our principles for a nationwide regulatory framework to Congress.[4] We have also worked closely with Senators Cassidy and Baldwin on introduction of the Health Data Use and Privacy Commission Act (S. 3620), and we are working to pass this important legislation into law.[5] Interoperability and privacy as policies go hand in hand, and HIA will continue to push for common-sense modernization of health privacy. Because of our separate work on privacy, HIA focused the work of the IWG purely on interoperability. As a result, the need for robust patient privacy is not addressed directly in this report or recommendations.

[4] https://health-innovation.org/press-releases/2020/3/9/health-innovation-alliance-calls-on-congress-to-adopt-new-health-data-and-privacy-framework
[5] https://www.congress.gov/bill/117th-congress/senate-bill/3620/text?r=2&s=1

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Solutions
Snapshot

All recommendations will require work and partnership between the public and private sectors. We believe the private sector should lead with government support, and where applicable, we have included specific federal offices.

1. Data That Works for Patients and Providers at the Point of Care

RECOMMENDATIONS	RESPONSIBLE ENTITY
1.1 Allow patients to request all covered entities (providers and plans) help find and share their health information to improve care coordination.	HHS-OCR, CMS
1.2 Develop historical patient records that can be easily accessed, exchanged, and used in care delivery, including by digital tools that can make the information useful and digestible at the point of care.	
1.3 Reduce patient friction and provider burden by requiring detailed plan coverage information at the point of care, including pharmacy, medical services, and prior authorization information, and incentivizing its use.	ONC, CMS
1.4 Require consistent imaging standards and develop a national plan to make images and imaging devices interoperable, including sharing images through cloud-based storage options.	FDA, ONC
1.5 Ensure clinicians have access to common-sense clinical decision support tools for care delivery and clarify software that is not subject to medical device regulation.	Congress, FDA

2. Leverage State of the Art Medical Devices to Improve Patient Care

RECOMMENDATIONS	RESPONSIBLE ENTITY
2.1 Create an accelerated approval pathway for interoperable medical devices to increase access and competition.	FDA
2.2 Define interoperability standards and specifications across device classes through a designated public-private committee process.	FDA, ONC
2.3 Study the optimal uses of wearable data for different use cases and how to standardize the information.	NIH, FDA
2.4 Integrate information from remote monitoring devices and wearables as real-world evidence to inform submissions and post market surveillance for drugs and devices.	FDA

3. Establish Clear Protections from HIPAA Penalties for Patient Information Requests

RECOMMENDATIONS	RESPONSIBLE ENTITY
3.1 Congress should solidify in statute that covered entities will not be liable for HIPAA penalties for sharing patient information pursuant to a patient request to share that information.	Congress

4. Inform Medical Research and Innovation with Better Information

RECOMMENDATIONS	RESPONSIBLE ENTITY
4.1 Develop a streamlined, simple authorization for patients to share their health information with researchers at their discretion.	OCR, ONC
4.2 Connect electronic health records (EHRs) to research tools to allow patients and providers to locate clinical trials and help researchers find relevant patients.	HHS
4.3 Enable remote clinical trials through private and secure connectivity between devices and researchers.	FDA, NIH, ONC, NIST
4.4 Establish a single, accessible, searchable repository of clinical trials for use by patients, providers, and researchers.	NIH, HRSA

5. Social Determinants of Health

RECOMMENDATIONS	RESPONSIBLE ENTITY
5.1 Fund existing work to collect and standardize social determinants of health (SDOH) information to build toward consistent integration and use of SDOH in clinical care.	HHS
5.2 Fund community health workers and safety-net providers that are trusted and respected in underserved areas and give them access to population health tools.	CMS, ONC

6. Improve Public Health Data Collection and Reporting

RECOMMENDATIONS	RESPONSIBLE ENTITY
6.1 Standardize public health information, including laboratory data, within the next two years.	CDC, ONC
6.2 Support a model data use agreement for potential adoption by states and local public health authorities.	CDC, ONC
6.3 Integrate automated public health reporting tools into existing systems and workflows.	ONC, CMS
6.4 Ensure actionable public health information is being reported back to providers and others actively responding to public health crises.	CDC, CMS
6.5 Institute a transparent stakeholder process for data modernization modeled after public meetings held by the FDA to incorporate experts from the private sector.	CDC

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Detailed
Solutions

1. Data That Works for Patients and Providers at the Point of Care

Ability of Patients to Request Covered Entities Submit Access Requests on Their Behalf

Problem – Patients have a right of access to their own health information through the HIPAA Privacy Rule, but patients must track down their information from each prior encounter to build a more complete picture of their health care.

Status – In the 2020 HIPAA proposed rule, the Office for Civil Rights (OCR) proposes to allow patients to request that covered entities submit requests to another health care provider and to receive back the requested patient information into an EHR.[6] This proposed requirement limits the data to that contained in a provider electronic health record so that plans and providers may submit these requests only to other providers and not plans. Implementation of the Payer-to-Payer Data Exchange requirements has been delayed by the Centers for Medicare & Medicaid Services (CMS) to allow for more technical specifications for payer data systems.[7]

SOLUTION 1.1

Patients should be allowed to request that covered entities submit requests for their health information to all other covered entities and that the covered entity requesting on behalf of the patient receive information from the other covered entity. In short, OCR should adjust its proposed policy to allow patients to request that providers and plans request their health information from other providers and plans, not just other providers. Additionally, CMS should implement the payer-to-payer data exchange requirements as soon as possible and make that data available through APIs to providers and patients as well.

Longitudinal Patient Record

Problem – Providers, patients, and plans lack a complete picture of an individual's health. At the bedside or in a clinic, decisions still rely on information gathered on intake forms and verbal histories provided by patients. Because providers have little time to review comprehensive notes when they are shared, the best information to determine proper treatment usually comes directly from the patient. Relevant context like family history and genetic information are rarely reviewed or available to inform clinical care.

Status – Implementation of Cures is ongoing and despite calls in the statute for support of health information in a "single, longitudinal format that is easy to understand," comprehensive patient records do not exist unless the patient has assembled them.[8] Even without historical patient information, providers continue to stress the overload of information in EHRs that contributes to provider burden and burnout.

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[6] https://www.federalregister.gov/documents/2021/01/21/2020-27157/proposed-modifications-to-the-hipaa-privacy-rule-to-support-and-remove-barriers-to-coordinated-care

[7] https://www.cms.gov/about-cms/obrhi/faqs

[8] 42 U.S.C. 300jj-19.

As the Patient Access API makes data more available, it will fail to generate a complete picture of an individual's health care without patients aggregating the information themselves or digital technologies to pull the information together and make it accessible and usable at the point of care.

SOLUTION 1.2

Government and industry should support the ability of patients to request their health information from all entities that have such information and import this data into a single, accessible, longitudinal record that can be stored, shared, searched, and ingested by digital tools to make the information useful. Industry should work with patients to develop longitudinal patient records that are shareable across systems and have aggregated, usable information for caregivers.

Availability of Eligibility Data through APIs

Problem – Patients and providers rarely know the exact details of an individual's health benefits while weighing care decisions. Without access to relevant benefit information, patients are unable to determine the specific costs they will incur during the course of their treatment. Much of the pricing information available or that will be available soon is generalized and not indicative of what individuals may end up paying or having covered. According to the Council for Affordable Quality Healthcare, $18.3 billion was spent on eligibility and benefit verification in 2021 with a potential savings of $9.8 billion if these processes were digitized.[9]

Status – Previous and current administrations and Congresses have taken great steps to increase health care cost "transparency." From requirements in the Medicare program for hospitals to publish master charge lists to Congressional passage and ongoing implementation of the No Surprises Act, patients are being promised a more predictable health care system specific to the charges they will incur for services. However, implementation of the real time benefit tools requirement from the 2021 Consolidated Appropriations Act could leave gaps in critical information if eligibility data is not included. Previous and current administrations have taken steps to standardize and digitize prior authorization processes, but much work is still needed, including consistent adoption among payers, including Medicaid, CHIP, and qualified health plans.

SOLUTION 1.3

ONC and CMS should make eligibility-specific information available from plans at the point of care through APIs to provide patients and caregivers real-time access to coverage information specific to an individual's benefits. Information available to patients and caregivers should include details of pharmacy coverage, medical services relative to location or facility, provider network status, and deductible and out-of-pocket limits and status. Once that data is available, providers should be incentivized to access and use it to inform patient options. Prior authorization should be an electronic process standardized consistently across payers with providers able to access, respond to, and exchange pertinent authorization information like denial reasons.

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9 https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf

Standardized Sharing of Images to Enable Consistent Access for Patients and Providers

Problem – Image files, such as CTs and MRIs, do not currently transfer between caregivers without specific patient intervention. Image files are large and often the file type and required software required vary between vendors. Patients can be stuck transporting CD-ROMs of previous images between providers, and providers can be stuck waiting for delivery of a CD-ROM from another provider following a HIPAA request to share that previous image. Lack of image sharing can lead to duplicative scans at greater cost to patients and the health care system.

Status – Image storage is often location or practice specific, with many providers unable to digitally share files with other practices or locations. Digital Imaging and Communications in Medicine (DICOM) is a widely recognized standard for transporting and storing images through picture archiving and communication systems (PACS). While DICOM is used by many health practices, the standard is not required or adopted across specialties or vendors.

SOLUTION 1.4

Consistent standards (such as DICOM) should be required across imaging products, and the FDA and ONC should work together with industry to develop a national plan to make medical images and imaging devices interoperable. PACS should connect to both EHRs nationwide and cloud-based storage options to make imaging more widely available to providers and patients.

Availability of Digital Tools to Access and Synthesize Information at the Point of Care

Problem – Providers already have an enormous amount of data through EHRs during clinical encounters, and as more elements are added to EHRs, more information will be available. Physicians face burdens trying to navigate through all the information to determine what is useful for each particular encounter and trying to access data from other providers related to previous encounters. Navigating EHRs takes up a significant portion of each clinician's day with more than 16 minutes spent on an EHR per each clinical encounter.[10] Additionally, doctors in the United States have clinical notes to sort through that are on average four times as long as those in other countries.[11]

Status – Clinical Decision Support (CDS) tools can connect to EHR data to help streamline information and synthesize data to be useful during the clinical encounter. FDA has issued draft guidance on regulating some CDS products as medical devices pursuant to Section 2060 of the 21st Century Cures Act.[12] FDA lists finalizing this guidance as a top priority for 2022, including CDS guidance on its "A-list."[13]

SOLUTION 1.5

FDA final guidance on CDS should create an environment where innovative technology companies are able to improve the use of data at the point of care through decision support. Congress should monitor implementation of CDS regulation carefully to ensure that process improvement tools are not stifled by the medical device review process while balancing patient safety and trust. Additional legislation may be needed to ensure the availability of digital tools on the front lines of health care delivery.

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[10]   https://www.acpjournals.org/doi/10.7326/M18-3684
[11]   https://www.fiercehealthcare.com/practices/u-s-doctors-clinical-notes-4-times-as-long-lance-downing
[12]   https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software
[13]   https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2022-fy2022

2. Leverage State of the Art Medical Devices to Improve Patient Care

Interoperability in Medical Devices

Problem – Emergency room clinicians must respond to multiple screens from multiple devices to coordinate care in life-or-death situations. Often the data from one device must be manually entered into an EHR, creating room for error. Ninety percent of those devices could be integrated with EHRs, saving clinician time and potentially patient lives.[14] Even though more remote monitoring technology is now available and being used, especially during the pandemic, there is no consistent flow of information between the monitoring devices and providers that is both standardized and secure.

Status – Functional interoperability of medical devices could yield an annual savings of more than $30 billion.[15] Nevertheless, current work by the FDA consists of a guidance detailing what should be included in a device submission that plans to include "interoperable" in its labeling, including suggestions that a manufacturer "perform testing" to ensure the devices continue to operate safely when data is received outside a normal range, and that the products use consensus standards.[16] Monitoring of patients remotely has proliferated during the pandemic, but CMS payment policies do not consistently support use of remote monitoring.

SOLUTIONS 2.1-2.2

Congress should create an accelerated approval pathway for interoperable medical devices to incentivize manufacturer engagement. The FDA should create a committee to help coordinate with the private sector and define interoperability standards and specifications across devices classes and to monitor progress with regular reports to Congress.[17]

Wearable Data

Problem – Wearable devices such as fitness trackers are popular, but the data they generate generally is not used for clinical care. The market for wearable technology is expected to grow 13.8 percent, reaching $118.16 billion by 2028. Many clinicians however do not view wearable data as clinically relevant for most use cases.

Status – CMS requested information on the integration of "patient generated data" into EHRs in a 2019 RFI but has not yet taken further action on the topic.[18] Current studies have found limited use for wearables in patient monitoring for things such as falls or weight loss.[19]

SOLUTIONS 2.3-2.4

The Department of Health and Human Services (HHS) should provide resources to study optimal uses of wearable data for different use cases and how to appropriately standardize the information across products. FDA should begin integrating information from remote monitoring devices and wearables as real-world evidence to inform applications and post market surveillance.

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[14] https://www.westhealth.org/wp-content/uploads/2015/02/The-Value-of-Medical-Device-Interoperability.pdf

[15] *Id.*

[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices?source=govdelivery&utm_medium=email&utm_source=govdelivery

[17] *See* https://jamanetwork.com/journals/jama-health-forum/fullarticle/2788095

[18] https://www.federalregister.gov/documents/2019/08/14/2019-16041/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other

[19] https://www.himss.org/resources/wearable-technology-applications-healthcare-literature-review

3. Establish Clear Protections from HIPAA Penalties for Patient Information Requests

Clarify in Statute That Covered Entities Will Not be Liable for HIPAA Penalties for Sharing Patient Information with Third Parties at Patient's Request.

Problem – Fear of penalties for violating the HIPAA Privacy Rule remains a large barrier to information sharing. HHS's rule implementing the 21st Century Cures Act emphasizes the ability of patients to share their own health information with third party applications through APIs required by the law. The majority of third-party applications are not subject to HIPAA, leaving medical societies and patient organizations concerned about how patient information might be shared and used.[20] Privacy concerns are one of the exceptions to compliance with the information blocking law. Despite encouragement from HHS, cautious general counsels may still favor not sharing patient information.

Status – HHS has clarified in an FAQ that covered entities are not liable under the HIPAA rules for any subsequent use or disclosure of health information received by a third-party app pursuant to a patient request to transfer that health information.[21] FAQs and similar guidance documents do not carry the weight of law and can change between administrations or even as policies adjust within an administration.

SOLUTIONS 3.1

Congress should solidify in statute that covered entities will not be liable for HIPAA penalties for sharing patient information pursuant to a patient request to share that information, codifying the current HHS policy included in OCR's FAQ 3009.[22] This codification will give covered entities the assurance they need to comply with information sharing requests and ensure that HIPAA does not remain a barrier to interoperability.

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20   *See* https://www.aha.org/press-releases/2020-03-09-statement-onc-final-rule
21   https://www.hhs.gov/hipaa/for-professionals/faq/3009/does-a-hipaa-covered-entity-bear-liability.html
22   *Id.*

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4. Inform Medical Research and Innovation with Better Information

Problem – Patients with rare or chronic conditions, including the undiagnosed, often have few treatment options available. Determining and accessing available experimental therapies by navigating various databases of clinical trials is time-consuming and cumbersome. Economic burdens associated with rare diseases are likely more than $1 trillion annually.[23] Similarly, researchers struggle to find robust patient cohorts to populate research trials, especially when those cohorts are to include patients with diverse backgrounds. Eighty-five percent of clinical trials fail to recruit enough patients.[24]

Status – EHRs contain a robust amount of patient information, but much of the specific data relevant to clinical research, such as genomic information, is either not available or siloed. Use of patient information for research is limited by HIPAA to instances where the patient has explicitly provided an authorization, but those authorizations are often use-specific. The ability to determine location of patients who may be relevant to a specific trial is limited also by HIPAA business associate agreements at each covered entity. As a result, there is no consistently available stream of patient information, even at the aggregate level.

SOLUTIONS 4.1-4.4

HHS should encourage the connection of EHRs to research tools and applications that would allow patients and providers to locate applicable clinical trials and also allow researchers to find relevant patients, where appropriate. OCR and ONC should work collaboratively with the private sector to develop a streamlined, simple authorization for patients to share their health information with researchers and providers to target relevant research for particular patients within existing workflow such as EHRs. Furthermore, connected devices should enable the ability for trials to be conducted remotely and across the country both privately and securely. Additionally, NIH and HRSA should provide resources for a public-private partnership to establish a single, accessible, searchable repository of clinical trials for use by patients, providers, and researchers.

[23] https://www.healthaffairs.org/do/10.1377/forefront.20220128.987667
[24] https://www.biopharmadive.com/spons/decentralized-clinical-trials-are-we-ready-to-make-the-leap/546591/

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5. Social Determinants of Health

Federal Support for Standards Development, Information Collection, and Information Translation Into Usable Data.

Problem – SDOH information such as economic, educational, and social factors are important to understanding and addressing health disparities and the overall health outcomes of individuals and communities. SDOH information is not currently collected or recorded reliably across care settings or in a standardized way. Much SDOH information is sensitive, and individuals may be reluctant to share it. Community health organizations and safety net providers lack resources to harness health information in EHRs, much less tools to collect and monitor SDOH information.

Status – Health disparities cost an estimated $93 billion in excess medical costs and $42 billion in lost productivity each year.[25] Initiatives like SIREN at UCSF and the Gravity Project are building the foundation of SDOH work, including the beginnings of standardization.[26] The United States Core Data for Interoperability (USCDI) includes an SDOH assessment, but patient screening for SDOH information remains difficult and inconsistent.

SOLUTIONS 5.1-5.2

HRSA and ONC should fund existing work to standardize SDOH information collection and data standardization to build toward consistent collection, integration, and use of SDOH in clinical care. Federal funding on information collection should focus on community health workers that are trusted and respected in the areas they will be collecting information.[27] More resources will be needed, however, to translate that information into common data elements that can be integrated into systems accessible to care providers in clinical workflows. Finally, community organizations and safety-net providers immersed in communities of need will need resources to access and use population health tools.

25 https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/
26 https://thegravityproject.net/; https://sirenetwork.ucsf.edu/
27 https://www.telehealthequitycoalition.org/documents/TEC-2022-White-Paper.pdf

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6. Improve Public Health Data Collection and Reporting

Standardized Data, Data Use Agreements, Automated Reporting, and Bidirectional Exchange

Problem – The COVID-19 public health emergency highlighted just how inadequate the nation's public health data system is and continues to be. Information from around the country still travels by fax machine to local public health offices and is eventually passed on to federal health authorities tasked with allocating resources across the nation to respond to the pandemic. Providers are burdened with varying rules in different jurisdictions and multiple reporting requirements depending on the public health authority requesting the information. Once information is reported up, it is rarely shared back with providers on the ground for use in treating patients or responding to crises.

Status – Congress has appropriated more than $1 billion to public health data modernization and continues to advance legislation to improve public health data collection, reporting, standardization, and holding federal public health authorities accountable. HHS and the White House continue to work toward standardizing and streamlining public health reporting and data standards, but much of work is being done outside of public view and without stakeholder engagement.

SOLUTIONS 6.1-6.5

The Centers for Disease Control and Prevention (CDC) and ONC should standardize public health information, including laboratory data, within the next two years. To encourage consistency in data collection and use across the country, CDC should support a model data use agreement for potential adoption by states and local public health authorities. Health IT vendors should integrate automated public health reporting tools into existing systems and workflows. Federal, state, local, and tribal public health authorities should ensure that actionable public health information is being reported back to providers and others actively responding to public health crises. CDC should contract with experts on data modernization activities and institute a transparent stakeholder process modeled after public meetings held by the FDA.

Conclusion

The promise of interoperability in healthcare is still very real, even though it has yet to be fully realized. By improving adoption and functionality in existing systems like EHRs and expanding interoperability efforts to other areas of health care, like public health and medical devices, we will begin to approach a truly liquid environment of usable health information. Automated collection and sharing of patient data through connected devices and information management systems could shepherd in an era of new medical innovation and precision medicine. Stakeholders at every end of the U.S. healthcare system stand to benefit from full implementation of the recommendations put forth above. HIA looks forward to working with everyone interested in making health care interoperability a reality.

Acknowledgments

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- 3M
- AHIMA
- Alliance of Community Health Plans
- Amazon Web Services
- American Academy of Ophthalmology
- American College of Cardiology
- American Society of Clinical Oncologists
- Association of Behavioral Health and Wellness
- Association of Clinical Research Organizations
- Athenahealth
- Blue Cross Blue Shield Association
- CARIN Alliance
- Chamber of Commerce
- Cover My Meds
- Experian Health
- Faster Cures/Milken Institute
- Federation of American Hospitals
- Glendor
- GO2 Foundation for Lung Cancer
- Google

- HIMSS
- IBM
- Invitae
- LexisNexis
- Linux Foundation
- LGBT Tech Partnership
- McKesson
- Michael J. Fox Foundation for Parkinson's Research
- Microsoft
- Myriad Genetics
- National Association of Community Health Centers
- National Association of Health Underwriters
- National Patient Advocate Foundation
- Olive
- Palantir
- Pharmacy Health IT Collaborative
- Research!America
- Siemens Healthineers
- Teladoc Health
- Tourette Association of America

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IWG Methodology

The workgroup met three times over a six-month period, with over 40 organizations participating across the discussions, representing providers, insurers, tech companies, patient advocates, and others.

The Interoperability Workgroup kicked off on October 20, 2021, by establishing goals of the workgroup and the process in which participants would engage. After a brief overview of current policy and how the current and previous administrations identified interoperability, information blocking, and protected health information access as priorities, participants shared specific examples of areas they have experienced limited interoperability. These include the lack of consistent and timely data exchange during the pandemic, the lack of enforcement of existing interoperability rules, privacy risks associated with third-party applications, and a lack of consistent rules on how data is shared.

Workgroup members recognized lack of enforcement as a key issue, specifying ambiguity over the OCR, ONC, or the Federal Trade Commission's role in administering interoperability requirements and associated privacy protections. The privacy discussions highlighted the lack of harmonization between state and federal laws, leading to a patchwork of differing regulations making it difficult for providers to comply. Further, the limitations of the Health Insurance Portability and Accountability Act (HIPAA) regarding third-party applications coupled with a lack of patient awareness and consent concerned many of the participants.

The second meeting on December 9, 2021, focused on integrating data from different systems into interoperable exchange. Before the second meeting, ONC released its goals for interoperability including improved data sharing between providers, expanding patient access to personal data, and automated public health data reporting. Using ONC's goals as a baseline for discussion, workgroup members considered potential solutions to improving patient access to their own health information while enabling patient-directed exchanges but reiterated the need for improved data standards.

Workgroup members discussed the need to integrate data from different systems, including pharmacy and vaccination records, to allow providers and patients to make better informed care decisions. However, members acknowledged that bringing in diverse sets of data is challenging without industry standards. Members did agree different data elements should be integrated in ways that are usable, accessible, comprehensive, and comprehendible.

Further, the workgroup touched on the need to improve the patient consent process for clinical trials and research, and the steps needed to standardize Social Determinants of Health data. Members believed the U.S. should identify bidirectional standards to improve state-wide data sharing and general exchange nationally, while highlighting the lack of technological resources for providers in underserved areas to collect and report data.

On February 16, 2022, HIA staff introduced initial draft recommendations based on the discussion and feedback from participants in the prior two meetings. The feedback and insights from workgroup members helped tailor the recommendations down to six key areas: data at the point of care, connected devices, a HIPAA safe harbor for fulfilling patient access requests, patient connected research, social determinants of health, and public health. With overarching goals, the workgroup focused on implementation and potential problems to avoid, including provider training and burden.

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