



ACT | The App Association

Testimony

of
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on
Smart Health: Empowering the
Future of Mobile Apps

before the
House Committee on Science, Space, &
Technology, Subcommittee on Research
and Technology

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2141 Rayburn House Office
Building





Subcommittee Chair Comstock, Ranking Member Lipinski, and distinguished members of the Committee: My name is Morgan Reed and I am the executive director of ACT | The App Association. I thank you for holding this important hearing on “smart health” and empowering the future of mobile apps.

ACT | The App Association represents more than 5,000 app companies and technology firms around the globe. As the world has quickly embraced mobile technology, our members have been creating innovative solutions to improve workplace productivity, accelerate academic achievement, and help people lead healthier lifestyles.

Additionally, we are spearheading an effort through our Connected Health Initiative to clarify outdated health regulations, incentivize the use of remote patient monitoring, and ensure the environment is one in which patients and consumers can see improvement in their health.¹ This coalition of leading mobile health companies and key stakeholders works to ensure Congress, the Food and Drug Administration (FDA), and Department of Health and Human Services (HHS) adopt policies that encourage mobile health innovation and keep sensitive health data private and secure.

In my testimony today, I elaborate on the following key messages:

- Mobile health apps offer potential to positively transform the American healthcare system. Without improvements to interoperability and reimbursement for using technologies like remote patient monitoring, we risk increased costs, and harm to patients.
- To reach the potential mobile health apps hold, clarity in legal and regulatory responsibility is needed. In particular, guidance regarding Health Insurance Portability and Accountability Act privacy and security rules in the context of cloud computing must be updated.
- While well-intentioned, law enforcement efforts to get access to data on devices and in the cloud pose major risks to data security and to businesses trying to manage data. Complying with both law enforcement and NIST security and data requirements, including recommendations on encryption, create a Hobson’s choice for our industry.



The Potential of Mobile Apps and Health

In existence less than a decade, the app industry has experienced explosive growth alongside the rise of smartphones. As the most rapidly adopted technology in human history, these devices revolutionized the software industry. I urge you to review our recently-released *State of the App Economy*,² which provides further information and statistics on this innovative industry that continues to grow while creating jobs and revolutionizing how consumers work, play, and manage their health. I'd also like to note that small companies and startups have thrived in the mobile marketplace. They currently represent 82% of the top app makers, dominate the revenue rankings, and drive innovation in the mobile economy.

Connected technology has the potential to radically improve the American healthcare system. As Americans have rapidly adopted mobile technology, our member companies have been producing and investing in innovative products and solutions across modalities and segments of the economy, with no stronger an example than healthcare. With 60% of the population already using mobile apps to help track their conditions and make informed choices about their health,³ mobile-app enabled telehealth and remote monitoring of patient-generated health data (PGHD) continues to represent the most promising avenue for improving care quality while lowering costs. Examples from ACT | The App Association's membership include:

- Atlanta-based Rimidi⁴ is a company showing the path forward with its Diabetes+Me app, which has demonstrated better patient outcomes at reduced cost.⁵ Goldman Sachs projects that connected health solutions like Rimidi's will reduce healthcare costs by \$305 billion.⁶ Rimidi uses both the "bring your own device" (BYOD) model as well as connected glucometers to better understand and improve the treatment of diabetes. Physicians are using the Rimidi platform to monitor their patients' glucose levels, as well as to help their patients determine the correct balance of insulin more efficiently.
- AirStrip^{®7} technology is a critical tool to keeping doctors informed on patient vitals while they're still in the ambulance. The company's products use Department of Defense-level encryption that allows doctors to remotely view live patient waveform data from multiple devices and systems on a single mobile screen securely, in advance of the patient entering a hospital room.



- CareSync⁸ provides a software platform that digitally connects doctors, patients, and caregivers, reducing the paper chase burden for MDs and delivering better care to happier patients, including chronic care management for Medicare.

Even the indirect benefits of connected health are astonishing. For example, Apple’s ResearchKit connects medical researchers with volunteers who want to share health data for scientific study. The platform provides no direct revenues for Apple, but it is revolutionizing how studies are conducted and accelerating the progress of medical research. In just 24 hours after its introduction, 11,000 iPhone users signed up for a Stanford cardiology study. Before ResearchKit, that level of engagement would have required 50 medical centers to each spend an entire year finding volunteers. I will note for the Committee that we recently provided written input to the FDA expanding on the benefits of our members’ innovative technologies in the clinical trial setting, which we urge you to review.⁹

Clearly, we have only seen the beginning of what connected health can bring our country, but we know there is incredible promise. However, there is also incredible need for these innovations that will only increase over time.

By 2050, there will be 83.7 million Americans over age 65—twice the amount from 2012. Eighty percent will have at least one chronic condition.

For example, consider the aging population of the United States. By 2050, there will be 83.7 million Americans over age 65—twice the amount from 2012.¹⁰ Eighty percent will have at least one chronic condition.¹¹ With a large portion living in rural areas or far from loved ones who could offer support, the age group’s rapid growth will severely strain public and private health resources.¹²

Advanced personal emergency response systems (PERS) are an example of the technology that can empower older populations and help them live comfortably in their homes years longer than today’s norm. Today, a PERS is typically a single button worn around the neck that directly connects to emergency services when pushed—made famous by the line “Help! I’ve fallen and I can’t get up!”

A far more sophisticated PERS will be packed with sensors and enabled by mobile apps that can track blood sugar, blood pressure, heart rate, biomarkers for medication adherence, geofencing for Alzheimer’s patients, and much more. These sensors will be small enough to fit in a watch and will connect to a loved one’s phone, a physician’s tablet, and a medical record system.

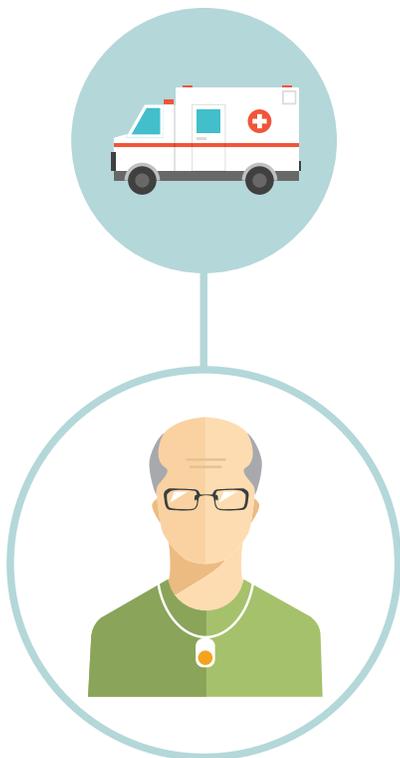


Non-wearables empowered by mobile health apps will matter as well, and there are some products already helping our rapidly aging population. For example, the Beddit is a mattress strap that monitors heart rate and sleep patterns.¹³

Even more sophisticated technology, such as the Microsoft Kinect, allows users to interact naturally with computing technology.¹⁴ This innovative solution can be used by physical therapists to allow patients to do therapy at home after a knee replacement, while still accurately measuring flex and strength.

This increasingly connected approach to healthcare will lower costs,¹⁵ empower aging populations to live at home longer, and allow physicians and loved ones to help with care in an efficient way. Individuals and their care teams will also have a more complete view of health information, allowing for earlier detection of issues.

PERS of today



PERS of the future





Legal Uncertainty Threatens Health Data Privacy and Security

To reach the potential mobile health apps hold, transparency in legal and regulatory responsibilities is a necessity. Increased predictability and clarity in the expectations and obligations for any organization are directly correlated to increased investment and innovation. Today, there is much room for improvement across a number of important contexts. Namely, mobile health app developers face sustained uncertainty around data storage and the cloud.

Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules

The Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules provide a set of minimum standards for protecting all electronic Protected Health Information that a Covered Entity and Business Associate create, receive, maintain, or transmit.¹⁶ The concerns addressed by these laws are taken seriously by mobile health app developers, and our members work to meet the letter and spirit of the law.

However, relevant HIPAA privacy and security rules and guidance applicable to mobile apps have not been updated since before the introduction of the iPhone, and the persistent lack of clarity around HIPAA applicability in a mobile environment prevents many patients from benefiting from these services. As a result, many physicians are reluctant to receive health readings from their patients electronically, and hospital systems are discouraged from adopting patient-centered technologies. To date, clear guidance does not exist to explain whether physicians and patients can text or email each other.

To address this need we worked with Members of Congress to attain an explicit, public commitment from HHS Secretary Burwell to work with ACT | The App Association in 2014,¹⁷ specifically to:

- Provide up-to-date and clear information about what is expected of technology companies for compliance with the HIPAA rules, and identify the implementation standards that can help technology companies conform to the regulations;
- Provide more clarity on HIPAA obligations for companies and services that store data in the cloud; and
- Engage regularly with technology companies to provide compliance assistance.



We welcomed these commitments in 2014, but have seen little evidence of meaningful follow through. Up-to-date and clear information about obligations under HIPAA is critical. While HHS has recently issued guidance with specific scenarios which may be helpful in a narrow range of circumstances,¹⁸ more guidance and documentation is needed.

Threats to Encryption in Protecting Health Data and Patient Privacy

No data is more personal to Americans than their own health data. ACT | The App Association members appreciate this, and put extensive resources into ensuring the security and privacy of sensitive health data to earn the trust of consumers, hospital systems, and providers. Fully leveraging technical measures, including end-to-end encryption (defined as a set of mathematically expressed rules for rendering data unintelligible by executing a series of conversions controlled by a key), is a critical element to accomplishing this. For example, the use of encryption is critical to meeting obligations under the above-noted HIPAA security and privacy rules.

More broadly, encryption enables key segments of the economy, from banking to national security, by protecting access to, and the integrity, of data. Since October of 2009, when the HITECH Act's enactment started requiring reporting of breaches, 1,473 health data breaches have occurred (a qualifying breach impacted 500 or more people); in 2015 alone there were 253 healthcare breaches representing a collective compromising of over 112 million electronic health records.¹⁹ Encryption's role should not be understated – without encryption, entire economies and industries are put at a significantly heightened risk of their data being compromised.

The National Institute for Standards and Technology (NIST) itself currently plays an important role in promoting the use of encryption. NIST's Computer Security Resource Center (CSRC) facilitates broad sharing of information security tools and practices, provides a resource for information security standards and guidelines, and identifies key security web resources to support users in industry, government, and academia.²⁰ NIST also provides the Cryptographic Module Validation Program (CMVP) that validates cryptographic modules to Federal Information Processing Standards (FIPS) 140-1 Security Requirements for Cryptographic Modules, and other FIPS cryptography-based standards.²¹ Further, NIST SP 800-66, An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, lists HIPAA-related storage security needs, and describes the need to encrypt and decrypt electronic protected health information.²²



Despite the important role encryption plays, some interests persist in demanding that “back doors” be built into encryption for the purposes of lawful access. We reject such proposals as mandates that degrade the safety and security of patient information, and the trust of patients. Worse still, these “back doors” could create vulnerabilities that are guaranteed to be exploited by state-backed hackers and criminals, furthering the kinds of “ransom-ware” situations, such as that faced by Hollywood Presbyterian Medical Center we all recently learned about.²³ Finally, these proposals also threaten the work of NIST’s CSRC to improve data security generally, and specifically in the health context.

In a recent court action against Apple, the Department of Justice has, using the All Writs Act as justification, taken steps to establish an unparalleled precedent that would allow it to compel software modification, forcing any company to re-engineer its code to provide government access, undermining the trust of its customers.²⁴ Due to the ubiquity of software in our lives, these mobile health apps which rely on strong encryption are directly impacted by such a policy. We are deeply concerned that the government’s request charts a dangerous path that would have a grave impact on app makers, and a chilling effect on innovation. We urge NIST to take all steps necessary to protect the role of encryption.





Empowering Mobile Health Apps Requires Interoperability

Coupled with electronic health record (EHR) data stored in standardized formats with interoperability facilitated by such means as application programming interfaces (APIs),²⁵ mobile health apps provide the capability for analytic, as well as near real-time, alerting. The use of APIs to design solutions and platforms for data streams from multiple and diverse platforms and sources (including PGHD) will directly contribute to areas of needed improvement in the healthcare sector, including information silos, data blocking, and deficient patient engagement in care.

The utilization of open and consensus-driven and voluntary standards is a long-standing federal policy that promotes effective and efficient technology and innovation in the global marketplace.²⁶ Open standards are a cornerstone to interoperability, and will promote innovation in the eHealth marketplace.

To encourage a more widespread adoption of interoperable health information technology, the American Recovery and Reinvestment Act of 2009 calls for the Office of the National Coordinator (ONC) for Health IT, in consultation with NIST, to recognize a program for the voluntary certification of health information technology as being in compliance with applicable certification criteria to meet defined meaningful use requirements.²⁷

In collaboration with ONC, NIST has developed the functional and conformance testing requirements, test cases, and test tools to support this health IT certification program. While CMS Acting Administrator Andy Slavitt has indicated that the Meaningful Use program's days are numbered²⁸ and that CMS will not tolerate data blocking or business models that prevent or inhibit the data from flowing around the needs of the patient, NIST should build on its work on standards for health IT interoperability communication moving forward.

Further, technology, standards, and products are available today to facilitate the data exchange of patient data to a clinical EHR, including health reporting network interfaces that establish standards for exchange of patient summaries between remote monitoring systems and certified EHR technologies. NIST houses important efforts to promote standard-based medical device interoperability and communication.

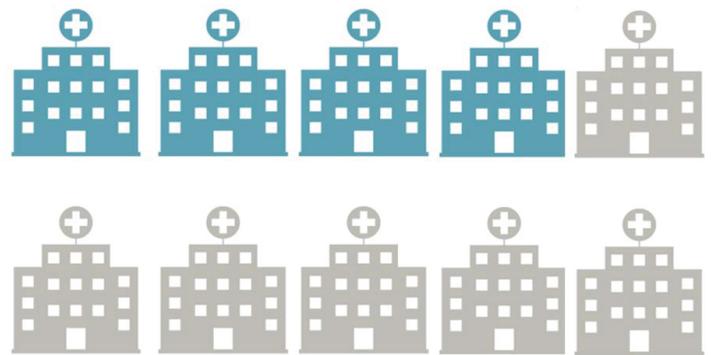


Private-public partnerships have created valuable standards, including: the Continua Alliance’s Design Guidelines,²⁹ Health Level 7 (HL7),³⁰ ISO 12052 (Health informatics -- Digital imaging and communication in medicine including workflow and data management),³¹ and the Integrating the Healthcare Enterprise (IHE) initiative,³² among others.

The use of open APIs and standards for interoperability between providers as well as between remote patient monitoring devices and EHRs—all enabled by apps—is critical to improving patient outcomes. According to research from ONC, forty-one percent of hospitals nationwide routinely have necessary clinical information electronically available from outside providers or sources when treating a patient.³³

It would also enable systemic engagement between patients, health care providers, and other stakeholders. Such voluntary industry standards along with consensus on specifications for interoperability between remote monitoring systems and EHRs already exist, continue to be developed and refined, and are currently available for use in systems and products.

For these reasons, we urge this Committee to work to enable interoperability in healthcare, and supports NIST’s role in ensuring the interoperability needed to empower mobile health apps.



Only 4 out of 10 hospitals routinely use electronically available clinical information from outside providers when treating a patient.

Source: ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement



Reimbursement’s Role in Empowering Mobile Health Apps

Healthcare providers must now shift from fee-for-service to value-based payments, and the resulting incentives favor outcomes more than procedures. This transition significantly elevates the value of connected health data that comes from remote patient monitoring, chronic condition management, wearable sensors, and apps.

Mobile health apps provide great opportunity to advance patient care, lessen hospitalizations, and boost patient involvement and investment in their own treatment. For example, a connected glucometer that periodically sends biometric data to a monitoring physician’s office allows for ease in care management and could also easily prevent an emergency room visit by detecting shock onset early.

Despite the demonstrated value these technologies hold for improving the American health system, statutory and regulatory constraints on Medicare reimbursement for health care professionals’ use of telehealth and remote patient monitoring technologies have long been a deterrent to advancement and adoption. Notably, Section 1834(m) of the Social Security Act has resulted in significant restrictions on telehealth services by adding odd and untenable requirements like “originating site” and “geographic” restrictions.³⁴ In addition, remote patient monitoring is unreasonably restrained by the Center for Medicare and Medicaid Services’ (CMS) policy decision to not provide direct coverage for payment purposes.

As a result, Medicare coverage for telehealth is startlingly deficient,³⁵ while reimbursement for remote patient monitoring is non-existent and denies reasonable reimbursement for the monitoring of patient generated health data that should be leveraged to improve care outcomes.³⁶

Despite a lack of support within subsidized medicine, the body of evidence demonstrating the potential benefits of remote monitoring of PGHD continues to grow, showing improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, and greater patient involvement in care, particularly for the chronically ill.³⁷



For example, the use of virtual chronic care management by the Department of Veterans Affairs resulted in a substantial decrease in hospital and emergency room use.³⁸ There is also a growing body of potential cost savings: by the end of 2016, mobile health solutions could represent up to \$340 billion in annual healthcare cost savings worldwide.³⁹

While ACT | The App Association has continued to urge CMS to incorporate telehealth and remote patient monitoring solutions under the existing fee-for-service reimbursement system to the greatest extent possible, great opportunity exists in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),⁴⁰ including the use of the Merit-based Incentive Payment System (MIPS)

By the end of 2016, mobile health solutions could represent up to \$340 billion in annual healthcare cost savings worldwide.

and Alternative Payment Models (APMs). MACRA will move Medicare from a quantity-based reimbursement payment model to one that is quality based. We are deeply engaged with CMS as it plans for MACRA’s 2019 effective date, and welcomes the opportunity to work with Congress on these issues.

It is for these reasons that we are a leading supporter of the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act,⁴¹ a careful and balanced approach that would lift Medicare’s arduous limitations on the use of telehealth, enable the use of remote patient monitoring technology for patients with chronic conditions, safeguard that new payment models will incorporate connected health technologies, ensure that these advanced solutions are a part of the Medicare Advantage program, and address discrete issues associated with the treatment of Americans who suffer strokes and who require dialysis treatment.

I should note for you that we are not addressing these reimbursement issues in a vacuum. Today, ACT | The App Association leads a diverse—and growing—coalition of more than 90 companies and associations that reside across the medical and technology communities which convenes on a regular basis to discuss the convergence of the healthcare industry, ways in which stakeholders can work together, and which advocates for these policies based on detailed consensus views.⁴²



Federal Agency Coordination is Key to Enabling Mobile Health Apps

To realize the full potential of a mobile health app-enabled “continuum of care,” the coordination of key federal agencies is essential, and I commend you for addressing this important topic in today’s hearing. NIST, the Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), HHS Center for Medicare and Medicaid Services (CMS), HHS Office of Civil Rights (OCR), and the Food and Drug Administration (FDA) all play key roles in empowering the future of mobile apps, and Congress’ continued focus is and will be needed to ensure that federal agency coordination remains top of mind.

In ACT | The App Association’s experience, agencies impacting mobile apps in the health space have some room for improvement in their coordination activities. As just two examples:

- Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA)⁴³ requires that the FDA, in consultation with ONC and the Federal Communications Commission (FCC), develop a proposed strategy and recommendations on a risk-based health information technology (IT) regulatory framework. While this proposed strategy was released in draft form in April 2014⁴⁴ and a later public forum was held in May of 2014,⁴⁵ it has not been finalized to date, and we have seen little meaningful coordination amongst FCC-FDA-ONC resulting from it..
- While CMS has commenced regulatory activity towards the 2019 implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)⁴⁶ which Congress has explicitly stated is to embrace remote patient monitoring of PGHD in evolving Medicare, ONC has separately announced that it will develop a policy framework for identifying best practices, gaps, and opportunities for the use of PGHD in research and care delivery through 2024.⁴⁷ Both of these significant activities—which ACT | The App Association is supportive of and invested in—are overlapping yet not in coordination.



Agency coordination will not only help avoid duplicative or conflicting regulations and parallel efforts, but will help agencies ensure that inquiries into opportunities are informed. NIST occupies a unique role in the federal government as a coordinator of other agencies. For example, in addition to statutory roles related to electronic health records,⁴⁸ standards coordination,⁴⁹ and information security standards and guidelines for federal agencies,⁵⁰ NIST leads the development of the NIST Cybersecurity Framework⁵¹ and the National Strategy for Trusted Identities in Cyberspace (NSTIC).⁵²

We are committed to working with this Committee, NIST, and other federal entities to explore new ways improve coordination and improve governance structure towards empowering mobile health apps.

Conclusion

Mobile health apps offer incredible benefits to the American healthcare system, but they will not reach full potential without a careful and coordinated effort between Congress, Federal agencies, and private stakeholders. As discussed above, without meaningful action to address important issues such as interoperability and reimbursement for using technologies like remote patient monitoring, we place countless patients' quality of care in jeopardy.

It is also important that clarity in legal and regulatory responsibilities be provided. Specifically, guidance regarding HIPAA privacy and security rules in the context of cloud computing must be updated, and the ability to use strong encryption should be protected. Finally, efforts to ensure close Federal agency coordination should be prioritized.

I thank you again for the opportunity to present testimony about the extraordinary mobile health app ecosystem. I look forward to our continued work together and pledge our support to help advance measures that empower mobile health apps.



End Notes

- 1 “Connected Health Initiative.” Available at: <http://connectedhi.com>.
- 2 <http://actonline.org/2016/01/04/act-the-app-association-releases-latest-app-industry-report/>.
- 3 Get Mobile, Get Healthy: The Appification of Health & Fitness Report, Mobiquity (2014), available at <http://www.mobiquityinc.com/mobiquity-white-papers?ref=mHealth-report-2014>.
- 4 <http://www.rimidi.com/>.
- 5 Lindsey Valenzuela, Lucienne Ide, Michael Jardula, Mena Salib, Jade Le. “Early Results Support Efficacy and Clinical Efficiency of Diabetes Management Decision Support Software for Blood Glucose.” Annual Diabetes Technology Meeting, San Diego, CA, October 2015.
- 6 Roman, D. H. & Conlee, K. D., “The Digital Revolution comes to US Healthcare,” Goldman Sachs (June 29, 2015), available at <http://www.scbio.org/resources/Documents/Internet%20of%20Things%20-%20Volume%205%20-%20The%20Digital%20Revolution%20comes%20to%20US%20HC%20-%20Jun%202029,%202015%5B1%5D.pdf>.
- 7 <http://www.airstrip.com/>.
- 8 <http://www.caresync.com/consumers/index.php>.
- 9 See comments of ACT | The App Association regarding the Food and Drug Administration’s Request for Comments, Using Technologies and Innovative Methods To Conduct Food and Drug Administration-Regulated Clinical Investigations of Investigational Drugs (Docket No. FDA-2015-N-3579) (filed Dec. 28, 2015), available at <http://actonline.org/wp-content/uploads/ACT-Comment-to-FDA-re-Clinical-Trials-122815.pdf>.
- 10 “An Aging Nation: The Older Population in the United States,” United States Census Bureau (May 2014). Available at: <http://www.census.gov/prod/2014pubs/p25-1140.pdf>.
- 11 “Healthy Aging: Improving and Extending Quality of Life Among Older Americans,” Center for Disease Control and Prevention (2009). Available at: http://www.cdc.gov/nccdphp/publications/aag/pdf/healthy_aging.pdf.
- 12 “Housing an Aging Rural America: Rural Seniors and their Homes,” Housing Assistance Council (October 2014). Available at: <http://ruralhome.org/storage/documents/publications/rreports/ruralseniors2014.pdf>.
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- 14 <https://dev.windows.com/en-us/kinect>.
- 15 “The Boomer Challenge,” Hospitals & Health Networks (January 2014). Available at: <http://www.hhnmag.com/Magazine/2014/Jan/cover-story-baby-boomers>.
- 16 45 CFR Part 160; 45 CFR Part 164 Subparts A and C.



17 Letter from ACT | The App Association, et al., to Reps. Tom Marino and Peter DeFazio, U.S. House of Representatives (September 15, 2014).

18 <http://hipaaqportal.hhs.gov/a/pages/helpful-links>.

19 https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf.

20 <http://csrc.nist.gov/>.

21 <http://csrc.nist.gov/groups/STM/cmvp/>.

22 <http://csrc.nist.gov/publications/nistpubs/800-66-Rev1/SP-800-66-Revision1.pdf>.

23 E.g., <http://www.engadget.com/2016/02/19/hospital-ransomware-a-chilling-wake-up-call/>.

24 <http://www.apple.com/customer-letter/answers/>.

25 The Center for Medicare and Medicaid Services (CMS) defines an API as “a set of programming protocols established for multiple purposes...[that] may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current ‘patient portals.’” 80 FR 16753.

26 See OMB Circular A-119 Revised, Federal Participation in the Development And Use of Voluntary Consensus Standards and in Conformity Assessment Activities (rev. Feb. 10, 1998), available at <http://www.whitehouse.gov/omb/rewrite/circulars/a119/a119.html>.

27 45 CFR Part 170 Subpart C.

28 <http://www.nist.gov/healthcare/testing/mutestmethod.cfm>.

29 <http://www.continuaalliance.org/products/design-guidelines>.

30 <http://www.hl7.org/implement/standards/index.cfm>.

31 http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43218.

32 http://www.ihe.net/About_IHE/.

33 https://www.healthit.gov/sites/default/files/briefs/onc_databrief25_interoperabilityv16final_081115.pdf.

34 See 42 CFR § 410.78.

35 For example, according to the Centers for Medicare & Medicaid Services (CMS), Medicare telemedicine reimbursement totaled a mere \$13.9 million in Calendar Year 2014. See <http://ctel.org/2015/05/cms-medicarereimburses-nearly-14-million-for-telemedicine-in-2014/>.



36 Medicare considers CPT Code 99091 (“Physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver”) as “bundled” into payment for other basic services (e.g., an office visit provided the same day or other services incident to the service provided) and therefore does not currently make separate payment for 99091.

37 See Hindricks, et al., *The Lancet*, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4. See also U.S. Agency for Healthcare Research and Quality (AHRQ) Service Delivery Innovation Profile, Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs (last updated Feb. 6, 2013), available at <http://www.innovations.ahrq.gov/content.aspx?id=3006>.

38 See Darkins, *Telehealth Services in the United States Department of Veterans Affairs (VA)*, available at <http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf>.

39 See SNS Telecom, *The mHealth (Mobile Healthcare) Ecosystem: 2015 – 2030 – Opportunities, Challenges, Strategies & Forecasts* (rel. Sept. 2015).

40 42 U.S.C. 1305.

41 S. 2484 (introduced Feb. 2, 2016). Companion legislation introduced as H.R. 4442 (Feb. 3, 2016). See also Letter from ACT | The App Association to Senators Schatz, Wicker, Cochrane, Cardin, Thune and Warner (sent Feb. 3, 2016), available at <http://actonline.org/wp-content/uploads/ACT-Ltr-of-Support-for-CONNECT-for-Health-Act-020316.pdf>.

42 E.g., Joint Comment to Senate Finance Committee’s Chronic Care Working Group (Jan. 26, 2016), available at <http://actonline.org/wp-content/uploads/Coalition-Letter-re-Senate-Finance-Chronic-Care-WG-012916.pdf>.

43 P.L. 112-144.

44 FDA, *FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework* (Apr. 2014), available at <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm390588.htm>.

45 79 FR 21473.

46 42 U.S.C. 1305.

47 <https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data>.

48 NIST’s roles in this context have been articulated in both Federal Health IT strategic plans (2008–2012 and 2011–2015) and in the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009.

49 Under the National Technology Transfer and Advancement Act (NTTAA), NIST manages assigned responsibility to coordinate federal, state, and local technical standards and conformity assessment activities, as well as coordinates with those in the private sector.

50 Title III of the E-Government Act of 2002 (P.L. 107-347).



51 <http://www.nist.gov/cyberframework/index.cfm>.

52 <http://www.nist.gov/nstic/>.



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